UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

In re: Metformin Marketing and Sales Practices Litigation	Case No. 2:20-cv-2324-MCA-MAH **JURY DEMAND**

CONSOLIDATED ECONOMIC LOSS CLASS ACTION COMPLAINT

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INTRODUCTION

1. This case arises from adulterated, misbranded, and unapproved metformin-containing drugs ("MCDs") that were designed, manufactured, marketed, distributed, packaged, and/or ultimately sold by Defendants (identified and defined below at Part II.C-H), in the United States, and that have been and remain the subject of one of the largest ongoing contaminated drug recalls ever in the United States. These MCDs are non-merchantable, and are not of the quality represented by Defendants.

2. Metformin, originally marketed under the brand name Glucophage and/or Glucophage XR, is an oral antihyperglycemic drug used as a first-line therapy in the treatment and management of type 2 diabetes. It is often referred to as the "gold standard" of diabetes management because it is well-tolerated and cost-effective.

3. Metformin was first discovered in 1922, and first marketed in the United States in 1995. Metformin is considered so critical to diabetes management that it is listed by the World Health Organization ("WHO") on its List of Essential Medicines.

4. In 2016, Metformin was the fourth-most prescribed medicine in the United States, with more than 81 million prescriptions of MCDs dispensed.

5. Metformin Hydrochloride ("Metformin HCL") is the generic version of Glucophage and/or Glucophage XR, a now-discontinued product made by EMD Serono,[1] which is the Reference Listed Drug ("RLD").

6. The Class Plaintiffs bring this action for economic damages on behalf of the millions of MCD consumers, as well as TPPs, who paid or made reimbursements for Defendants'

[1] EMD Serono is the biopharmaceutical business of Merck KGaA, Darmstadt, Germany.

adulterated, misbranded, and/or unapproved MCDs illegally manufactured, sold, labeled, marketed, and distributed in the United States. Defendants' MCDs were adulterated and/or misbranded (and thereby rendered worthless) through contamination with a probable human carcinogen known as N-nitrosodimethylamine ("NDMA") and were otherwise substandard to the Metformin HCL originally approved by the U.S. Food and Drug Administration ("FDA").[2]

7. According to FDA testing, the generic MCDs here contained NDMA contamination levels that were many times higher than the FDA's February 28, 2019 updated interim limits for NDMA impurities. The FDA has yet to release testing results for other nitrosamine impurities.

8. Upon information and belief, the NDMA contamination of Defendants' MCDs dates back many years, at which point Defendants had actual and/or constructive notice of the contamination.

9. At all pertinent times during this period, Defendants represented and warranted to consumers and TPPs that their generic MCDs were therapeutically equivalent to and otherwise the same as the RLDs, were fit for their ordinary uses, met the specifications of Defendants' FDA-approved labeling materials, and were manufactured and distributed in accordance with and following all applicable laws and regulations.

10. For years, however, Defendants willfully ignored warnings signs about the operating standards at several of the overseas manufacturing plants where Defendants' generic MCDs were manufactured for import to the United States, and knowingly and fraudulently manufactured, sold, labeled, marketed, and/or distributed adulterated and/or misbranded MCDs for purchase and reimbursement in the United States by consumers and TPPs.

[2] The International Agency for Research on Cancer ("IARC") and the U.S. Environmental Protection Agency ("EPA") both list NDMA as a probably human carcinogen.

11. The Class Plaintiffs paid for or made reimbursements for generic MCDs that were illegally and willfully introduced into the market by Defendants, causing the Plaintiff Class(es) to sustain economic damages. Defendants' generic MCDs were not fit for their ordinary use and Defendants have been unjustly enriched through the sale of these knowingly adulterated and/or misbranded drugs. Defendants' conduct also constitutes actionable common law fraud, consumer fraud, and other violations of state and federal law as set forth below.

PARTIES

A. Consumer Class Representatives

12. Plaintiff Joseph Brzozowski is a citizen and resident of New Jersey, who resides and is domiciled in Ocean View, New Jersey. During the class period, Plaintiff paid money for one or more of Defendants' MCDs. Defendants expressly and impliedly warranted to Plaintiff Brzozowski that their MCDs were the same as branded MCDs and/or were as described in Defendants' FDA-approved labeling materials. But in fact, Plaintiff Brzozowski bought a product that was not the same as his MCDs' respective RLDs. Had Plaintiff Brzozowski known the product was not the same as the RLD, Plaintiff Brzozowski would not have paid for Defendants' MCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Brzozowski would not have paid for Defendants' MCDs.

13. Plaintiff Michael Hann is a citizen and resident of California, who resides and is domiciled in San Francisco, California. During the class period, Plaintiff Hann paid money for one or more of Defendants' MCDs. Defendants expressly and impliedly warranted to Plaintiff Hann that their MCDs were the same as branded MCDs and/or were as described in Defendants' FDA-approved labeling materials. But in fact, Plaintiff Hann bought a product that was not the same as his MCDs' respective RLDs. Had Plaintiff Hann known the product was not the same as the RLD,

Plaintiff Hann would not have paid for Defendants' MCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Hann would not have paid for Defendants' MCDs.

14. Plaintiff Jacqueline Harris is a citizen and resident of New Jersey, who resides and is domiciled in Bridgeton, New Jersey. During the class period, Plaintiff Harris paid money for one or more of Defendants' MCDs. Defendants expressly and impliedly warranted to Plaintiff Harris that their MCDs were the same as branded MCDs and/or were as described in Defendants' FDA-approved labeling materials. But in fact, Plaintiff Harris bought a product that was not the same as her MCDs' respective RLDs. Had Plaintiff Harris known the product was not the same as the RLD, Plaintiff Harris would not have paid for Defendants' MCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Harris would not have paid for Defendants' MCDs.

15. Plaintiff Stelios Mantalis is a citizen and resident of New York, who resides and is domiciled in Queens County, New York. During the class period, Plaintiff Mantalis paid money for one or more of Defendants' MCDs. Defendants expressly and impliedly warranted to Plaintiff Mantalis that their MCDs were the same as branded MCDs and/or were as described in Defendants' FDA-approved labeling materials. But in fact, Plaintiff Mantalis purchased a product that was not the same as his MCDs' respective RLDs. Had Plaintiff Mantalis known the product was not the same as the RLD, Plaintiff Mantalis would not have paid for Defendants' MCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Mantalis would not have paid for Defendants' MCDs.

16. Plaintiff Mohammad Rahman is a citizen and resident of California, who resides and is domiciled in Alameda County, California. During the class period, Plaintiff paid money for one

or more of Defendants' MCDs. Defendants expressly and impliedly warranted to Plaintiff Rahman that their MCDs were the same as branded MCDs and/or were as described in Defendants' FDA-approved labeling materials. But in fact, Plaintiff Rahman bought a product that was not the same as his MCDs' respective RLDs. Had Plaintiff Rahman known the product was not the same as the RLD, Plaintiff Rahman would not have paid for Defendants' MCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Rahman would not have paid for Defendants' MCDs.

17. Plaintiff Kristin Wineinger is a citizen and resident of Indiana, who resides and is domiciled in Hendricks County, Indiana. During the class period, Plaintiff Wineinger paid money for one or more of Defendants' MCDs. Defendants expressly and impliedly warranted to Plaintiff Wineinger that their MCDs were the same as branded MCDs and/or were as described in Defendants' FDA-approved labeling materials. But in fact, Plaintiff Wineinger bought a product that was not the same as her MCDs' respective RLDs. Had Plaintiff Wineinger known the product was not the same as the RLD, Plaintiff Wineinger would not have paid for Defendants' MCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Wineinger would not have paid for Defendants' MCDs.

18. Plaintiff Elaine Wohlmuth is a citizen and resident of California, who resides and is domiciled in Sacramento County, California. During the class period, Plaintiff Wohlmuth paid money for one or more of Defendants' MCDs. Defendants expressly and impliedly warranted to Plaintiff Wohlmuth that their MCDs were the same as branded MCDs and/or were as described in Defendants' FDA-approved labeling materials. But in fact, Plaintiff Wohlmuth bought a product that was not the same as her MCDs' respective RLDs. Had Plaintiff Wohlmuth known the product was not the same as the RLD, Plaintiff Wohlmuth would not have paid for Defendants' MCDs.

Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Wohlmuth would not have paid for Defendants' MCDs.

B. The Third-Party Payor ("TPP") Class Representatives

19. Plaintiff MSP Recovery Claims, Series LLC ("MSPRC") is a Delaware series limited liability company with its principal place of business at 5000 S.W. 75th Avenue, Suite 400, Miami, Florida 33155. MSPRC's limited liability company agreement provides for the establishment of one or more specific series. All records of all series are maintained together with all assets of MSPRC.

20. Certain healthcare benefit providers have assigned their recovery rights to assert the claims alleged in this Complaint to Series LLCs of MSPRC. Pursuant to MSPRC's limited liability agreement, all rights arising from the assignment to its series (including the assignments discussed below), along with the right to bring any lawsuit in connection with that assignment (including those below), belong to MSPRC. As such, MSPRC has the right and power to sue defendants to recover the payments at issue in this action.

21. Certain series of MSPRC have executed irrevocable assignments of any and all rights to recover payments made on behalf of their assignors' health plan members and enrollees. These assignments authorize the series and, in turn MSPRC through its operating agreement, to pursue and enforce all legal rights of recovery and reimbursement for health care services and Medicare benefits. For example, and only to serve to further demonstrate standing, MSPRC alleges a few of the assignments below:

22. On March 20, 2018, Group Health Incorporated and Health Insurance Plan of Greater New York (otherwise known as "EmblemHealth" or "Emblem") irrevocably assigned all its rights and claims to recovery against any liable entity (including defendants) for payments made

on behalf of their enrollees under Medicare Parts A, B, and D to Series 16-08-483, a designated series of MSPRC. Specifically, the assignments provide the following:

> Assignor hereby irrevocably assigns, transfers, conveys, sets over and delivers to Assignee, and any of its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to all [claims against third parties], whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies that Assignor had, may have had, or has asserted against any party in connection with the [claims] and all rights and claims against primary payers and/or . . . third parties that may be liable to Assignor arising from or relating to the [claims], including claims under consumer protection statutes and laws, and all information relating thereto, as may be applicable.

23. On May 12, 2017, Summacare, Inc. ("Summacare") irrevocably assigned all its rights and claims to recovery against any liable entity (including defendants) for payments made on behalf of its enrollees under Medicare Parts A, B, and D to MSP Recovery, LLC ("MSP Recovery"). Specifically, the assignment provides the following language:

> [Summacare] hereby irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, and any of its successors and assigns, any and all of [Summacare's] right, title, ownership and interest in and to all Claims existing on the date hereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies for [Summacare] that [Summacare] had, may have had, or has asserted against any party in connection with the Claims and all rights and claims against primary payers and/or third parties that may be liable to [Summacare] arising from or relating to the Claims, including claims under consumer protection statutes and laws, and all information relating thereto, all of which shall constitute the "Assigned Claims".

24. On June 12, 2017, MSP Recovery irrevocably assigned all rights acquired under the Summacare Assignment to Series 16-11-509, a designated series of MSPRC:

> [Assignor] irrevocably assigns, sells, transfers, conveys, sets over and delivers to Assignee and its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to the [claims] (and all proceeds and products thereof) as such terms are defined in the Recovery Agreement dated May 12, 2017, by and among [Summacare] . . . and [MSP Recovery] . . . .

25. Summacare consented to, acknowledged, approved, and ratified the assignment from MSP Recovery to Series 16-11-509, which is memorialized in a letter dated September 5, 2018.

26. On March 20, 2018, Connecticare, Inc. ("Connecticare") irrevocably assigned all its rights and claims to recovery against any liable entity (including defendants) for payments made on behalf of its enrollees under Medicare Parts A, B, and D to Series 15-09-157, a designated series of MSPRC. Specifically, the assignment provides the following language:

> Assignor hereby irrevocably assigns, transfers, conveys, sets over and delivers to Assignee, and any of its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to all [claims against third parties], whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies that Assignor had, may have had, or has asserted against any party in connection with the [claims] and all rights and claims against primary payers and/or . . . third parties that may be liable to Assignor arising from or relating to the [claims], including claims under consumer protection statutes and laws, and all information relating thereto, as may be applicable.

27. Defendants have manufactured and distributed MCDs throughout the United States, for which plaintiff consumers made co-payments and TPPs, like MSPRC's assignors, paid. MSPRC's assignors made payments for Defendants' drugs in one or more of the following states or territories: Alaska, Alabama, Arkansas, Arizona, California, Colorado, Connecticut, Florida, Georgia, Hawaii, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Maine, Michigan, Minnesota, Missouri, Mississippi, Montana, North Carolina, New Hampshire, New Jersey, New Mexico, Nevada, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Virginia, Vermont, Washington, Wisconsin, West Virginia, the District of Colombia, and Puerto Rico. MSPRC's assignors' payments include those payments for Defendants' contaminated Metformin drugs, which were also manufactured, distributed, and sold during that same period. Below is a sample of payments that

MSPRC's assignors made for Defendants' Metformin drugs:

Date	State	Defendant	NDC Code	Amount Paid	Assignor
01/05/16	CT	Amneal Pharmaceuticals	53746017805	$15.56	Connecticare
03/30/16	NC	Aurobindo Pharmaceuticals	65862000899	$19.54	Connecticare
02/10/17	FL	Aurobindo Pharmaceuticals	65862001005	$15.71	Connecticare
02/05/13	MD	Heritage Pharmaceuticals	23155011701	$23.12	Emblem
06/03/13	NY	Teva Pharmaceuticals	00093104801	$22.93	Emblem
07/01/13	NY	Actavis Pharma	62037057110	$22.92	Emblem
11/27/15	OH	Heritage Pharmaceuticals	23155010310	$23.04	Summacare
02/10/16	OH	Actavis Pharma	00591271960	$17.00	Summacare
04/03/17	OH	Heritage Pharmaceuticals	23155011501	$48.60	Summacare

C. The Manufacturer Defendants

28. For ease of reading, this Master Class Complaint generally organizes Defendants by the distribution level at which they principally operate. The following Defendants manufacture the active pharmaceutical ingredient ("API") for Defendants' MCDs, or are closely affiliated with an entity that does so. Including certain Defendants in this section does not mean they are not properly classifiable as another type of defendant, or vice versa (e.g., a Defendant listed in this subsection may also be a distributor; a Defendant listed in the distributor subsection may also be an API manufacturer).

1. *The Teva/Actavis Entities*

29. Defendant Teva Pharmaceutical Industries Ltd. ("Teva") is a foreign company incorporated and headquartered in Petah Tikvah, Israel. Teva on its own and/or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. At all times material to this case, Teva has been engaged in the manufacturing, sale,

and distribution of adulterated and/or misbranded generic MCDs in the United States.

30. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation, with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054, and is a wholly-owned subsidiary of Teva. At all times material to this case, Teva USA has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded generic MCDs in the United States. Teva and Teva USA are collectively referred to as the Teva Defendants in this Complaint.

31. Actavis Pharma, Inc. ("Actavis Pharma") is a Delaware corporation with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054, and is Teva's wholly-owned subsidiary. At all times material to this case, Actavis Pharma has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded MCDs in the United States.

32. Actavis, LLC ("Actavis") is a Delaware corporation with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054, and is Teva's wholly owned subsidiary. At all times material to this case, Actavis has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded MCDs in the United States.

2. *The Emcure/Avet/Granules Entities*

33. Defendant Emcure Ltd. ("Emcure") is a foreign corporation with its principal place of business in Pune, India. Emcure on its own and/or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. At all times material to this case, Emcure has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded MCDs in the United States.

34. Upon information and belief, Emcure is the parent company of Defendant Heritage

Pharmaceuticals, Inc. d/b/a Avet Pharmaceuticals Inc., which is wholly owned by Emcure. Emcure states on its website that "[w]e have our own sales and marketing infrastructure in the United States through our subsidiary, Heritage."[3]

35. Defendant Heritage Pharmaceuticals, Inc. d/b/a Avet Pharmaceuticals Inc. (hereinafter "Avet" or "Heritage") is a corporation incorporated under the laws of Delaware with a principal place of business at One Town Center Boulevard, East Brunswick, New Jersey 08816. Avet conducts substantial business throughout the United States has been engaged in the manufacturing, distribution, and sale of defective MCDs throughout the United States. According to Avet's website, Avet is the "exclusive U.S. commercial operations of Emcure Ltd. … engaged in the acquisition, licensing, development, marketing, sale and distribution of generic and legacy branded pharmaceutical products for the U.S. prescription drug market."[4]

36. Defendant Avet boasts about its "vertically integrated global supply network" on its website.[5]

37. Defendant Granules USA, Inc.is a corporation incorporated under the laws of Delaware with a principal place of business at 35 Waterview Boulevard, Parsippany, New Jersey 07054. Granules USA, Inc. is a wholly-owned subsidiary of the Indian corporation Granules India Limited. Granules USA, Inc. conducts substantial business in the United States, and specifically in the States of New Jersey and Indiana. Granules USA, Inc. has been engaged in the manufacturing, distribution, and sale of defective MCDs throughout the United States.

38. Defendant Granules Pharmaceuticals, Inc. is a corporation incorporated under the laws of Delaware with a principal place of business at 3701 Concorde Parkway, Chantilly, Virginia

[3] https://www.emcure.com/aboutus (last visited June 27, 2020).
[4] http://avetpharma.com/about-us/ (last visited June 26, 2020).
[5] *Id.*

20151. Granules USA, Inc. is a wholly owned subsidiary of the Indian corporation Granules India Limited. Granules Pharmaceuticals, Inc. conducts substantial business in the United States, and specifically in the States of New Jersey and Indiana. Granules Pharmaceuticals, Inc. has been engaged in the manufacturing, distribution, and sale of defective MCDs throughout the United States.

39. On or about 2007, Heritage and Granules entered into a strategic alliance for the development, supply and marketing of generic pharmaceutical products, including MCDs, for the U.S. prescription drug market. Under the agreement, Granules develops and registers selected products for ANDA submission and Heritage retains exclusive sales and marketing rights to such products. Under the arrangement, Granules receives up front and milestone payments and the parties share net profits from the product sales.

40. At the time, Heritage's then-chief executive, Jeffrey Glazer, said: "[Heritage's] partnership with Granules represents another important milestone in Heritage's business model of utilizing strategic outsourcing for the development and manufacturing of quality generic products. Granules PFI technology represents a significant cost advantage for high-load, high-volume generic products, and will provide us with unprecedented economies of scale for the products under our agreement."

3. *The Amneal Entities*

41. Defendant Amneal Pharmaceuticals, Inc. ("Amneal") is a Delaware corporation with its principal place of business at 400 Crossing Blvd., Bridgewater Township, NJ 08807. At all times material to this case, Amneal has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded MCDs in the United States.

42. Defendant Amneal Pharmaceuticals LLC is a corporation incorporated under the

laws of Delaware with a principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807. Amneal conducts substantial business in the United States, and specifically in the States of New Jersey and California. Amneal has been engaged in the manufacturing, distribution, and sale of defective MCDs throughout the United States.

43. Defendant AvKare, Inc. ("AvKare") is a Delaware corporation with its principal place of business at 615 N. 1st Street, Pulaski, TN 38478. Upon information and belief, AvKare is a wholly-owned subsidiary of Amneal. At all times material to this case, AvKare has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded MCDs in the United States. On information and belief, AvKare repackages and/or relabels MCDs manufactured by Amneal.

4. *Aurobindo Pharma, Ltd. Entities*

44. Defendant Aurobindo Pharma, Ltd. ("Aurobindo") is a foreign corporation with its principal place of business at Plot no. 2, Maitrivihar, Ameerpet, Hyderabad-500038 Telangana, India, and a United States headquarters at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520. Aurobindo on its own and/or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. At all times material to this case, Aurobindo has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded MCDs in the United States.

45. Defendant Aurobindo Pharma USA, Inc. ("Aurobindo USA") is a Delaware corporation with its principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520. It is a wholly-owned subsidiary of Aurobindo. At all times material to this case, Aurobindo USA has been engaged in the manufacturing, sale, and distribution of MCDs in the United States.

46. Defendant Aurolife Pharma, LLC ("Aurolife") is a Delaware limited liability company with its principal place of business at 2400 U.S. 130, North, Dayton, New Jersey 08810. It is a wholly-owned subsidiary of Aurobindo USA. At all times material to this case, Aurolife has been engaged in the manufacturing, sale, and distribution of MCDs in the United States.

47. Aurobindo, Aurobindo USA, and Aurolife are collectively referred to as the Aurobindo Defendants in this Complaint.

48. Aurobindo's metformin API was supplied in large part to itself due to its vertically integrated supply chain. "Aurobindo adds value through superior customer service in the distribution of a broad line of generic pharmaceuticals, leveraging vertical integration and efficient controlled processes."[6]

5. *The Alkem/Ascend Entities*

49. Defendant Alkem Laboratories Ltd. is a foreign entity headquartered in Mumbai, India. Defendant Alkem states on its website that the United States is the "focal point" of Alkem's international operations, and that "we manufacture and supply a wide-range of generics … in the United States."[7] Alkem on its own and/or through its subsidiaries, including wholly-owned subsidiary Ascend, regularly conducts business throughout the United States and its territories and possessions. On its website, Alkem states that "[f]or more information about Alkem's operations in the US, please visit http://www.ascendlaboratories.com."8 At all times material to this case, Alkem has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded MCDs in the United States.

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[6] Aurobindo USA, OUR STORY, https://www.aurobindousa.com/company/our-story/ (last accessed July 6, 2020).
[7] https://www.alkemlabs.com/us.php (last visited June 26, 2020).
[8] *Id.*

50. Defendant Ascend Laboratories, LLC is a New Jersey corporation with a principal place of business at 339 Jefferson Road, Suite 1010, Parsippany, New Jersey 07054. Ascend is a wholly owned subsidiary of Alkem, and Ascend conducts substantial business throughout the United States. Ascend has been engaged in the manufacturing, distribution, and sale of defective MCDs in the United States.

D. Retail Pharmacy Defendants

51. Retail pharmacies have supply arrangements with manufacturers. They stand in direct contractual privity with consumers, given that retail pharmacies (be they brick-and-mortar or mail-order) are the entities that dispensed and received payment for the adulterated and/or misbranded MCDs for which consumers paid and TPPs reimbursed.

52. The following Defendants are collectively referred to as the "Pharmacy Defendants."

1. *Walgreens*

53. Defendant Walgreens Boots Alliance, Inc. ("Walgreens") is a national retail pharmacy chain incorporated in the State of Delaware with its principal place of business located at 108 Wilmot Road, Deerfield, Illinois 60015.

54. Walgreens is one of the largest retail pharmacy chains in the United States, offering retail pharmacy services and locations in all 50 states, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands. As of August 31, 2018, Walgreens operated 9,560 retail pharmacies across the United States, with 78% of the U.S. population living within five 5 miles of a store location. In addition, Walgreens recently purchased 1,932 more store locations from rival Rite Aid Corporation, further consolidating the industry. Walgreens' sales amounted to a staggering $98.4 billion in 2018, most of which are generated for prescription sales. Walgreens accounts for nearly 20% of the U.S.

market for retail prescription drug sales.

55. Walgreens is one of the largest purchasers of pharmaceuticals in the world, and according to its Form 10-K for 2018, the wholesaler AmerisourceBergen "supplies and distributes a significant of generic and branded pharmaceutical products to the [Walgreens] pharmacies."

56. In or about 2017, Walgreens acquired control of Diplomat Pharmacy. "Walgreens," as defined herein, includes any current or former Diplomat pharmacy.

57. Defendant Walgreens sold a large portion of the adulterated and/or misbranded MCDs to U.S. consumers and TPPs during the class period as defined below.

2. *CVS*

58. Defendant CVS Health Corporation ("CVS Health") is a national retail pharmacy chain incorporated in Delaware with its principal place of business located at One CVS Drive, Woonsocket, Rhode Island 02895.

59. As of March 31, 2019, Defendant CVS Health maintained approximately 9,900 retail pharmacy locations across the United States, making it one of the largest in the country. Defendant CVS Health also operates approximately 1,100 walk-in medical clinics and a large pharmacy benefits management service with approximately 94 million plan members.

60. According to its 2018 Annual Report, Defendant CVS Health's "Pharmacy Services" segment:

> provides a full range of pharmacy benefit management ("PBM") solutions, including plan design offerings and administration, formulary management, retail pharmacy network management services, mail order pharmacy, specialty pharmacy and infusion services, Medicare Part D services, clinical services, disease management services and medical spend management. The Pharmacy Services segment's clients are primarily employers, insurance companies, unions, government employee groups, health plans, Medicare Part D prescription drug plans ("PDPs"), Medicaid managed care plans, plans offered on public health insurance

exchanges and private health insurance exchanges, other sponsors of health benefit plans and individuals throughout the United States.

61. CVS Health's Pharmacy Services segment generated U.S. sales of approximately $134.1 billion in 2018.

62. CVS Health's Retail/LTC segment is responsible for the sale of prescription drugs and general merchandise. The Retail/LTC segment generated approximately $84 billion in U.S. sales in 2018, with approximately 75% of that attributed to the sale of pharmaceuticals. During 2018 the Retail/LTC segment filled approximately 1.3 billion prescriptions on a 30-day equivalent basis. In December 2018, CVS's share of U.S. retail prescriptions accounted for 26% of the United States retail pharmacy market.

63. In or about 2015, CVS Health acquired all of Target Corporation's pharmacies. "CVS," as defined herein, includes any current or former Target pharmacy.

64. In 2014, CVS Health and wholesaler Cardinal Health, Inc. ("Cardinal") established a joint venture to source and supply generic pharmaceutical products through a generic pharmaceutical sourcing entity named Red Oak Sourcing, LLC ("Red Oak"), of which CVS Health and Cardinal each own fifty percent. Most or all of the MCDs purchased by CVS Health were acquired through this joint venture with Cardinal.

65. Defendant CVS Health sold a large portion of the adulterated and/or misbranded MCDs to U.S. consumers and TPPs during the class period as defined below.

3. *Walmart*

66. Defendant Walmart Stores, Inc. ("Wal-Mart") is a Delaware corporation with its principal place of business in Bentonville, Arkansas.

67. According to Defendant Wal-Mart's 2018 Form 10-K, Wal-Mart maintains approximately 4,769 retail locations in all fifty states nationwide and the District of Columbia and

Puerto Rico (including supercenters, discount stores, and neighborhood markets and other small format locations). Most or all of these locations have Wal-Mart health and wellness products and services, which includes prescription pharmaceutical services. There are another approximate 600 Sam's Club locations across the United States, all or nearly all offering prescription pharmaceutical services.

68. Defendant Wal-Mart (including Sam's Club) sold a large portion of the adulterated and/or misbranded MCDs to U.S. consumers and TPPs across the country during the class period as defined below.

4. *Rite-Aid*

69. Defendant Rite-Aid Corporation ("Rite-Aid") is a Delaware corporation with its principal place of business in Camp Hill, Pennsylvania.

70. Defendant Rite-Aid sold a large portion of the adulterated and/or misbranded MCDs to U.S. consumers and TPPs during the class period as defined below.

5. *"John Doe" Pharmacies*

71. Upon information and belief, one or more additional pharmacies distributed adulterated, misbranded, and/or unapproved MCDs that were ultimately purchased by consumer class members, or reimbursed for by TPP class members. The true names, affiliations, and/or capacities of John Doe Pharmacies are not presently known. However, each John Doe proximately caused damages to Plaintiffs as alleged below, and each John Doe is liable to Plaintiffs for the acts and omissions alleged below as well as the resulting damages. Plaintiffs will amend this Master Class Complaint to allege the true names and capacities of the John Does when evidence reveals their identities.

E. "John Doe" Wholesaler Defendants

72. Wholesalers are entities that purchase, among other things, drugs from finished-dose

manufacturers and sell or provide those drugs to retail pharmacies and others.9

73. Upon information and belief, one or more wholesalers distributed adulterated, misbranded, and/or unapproved MCDs that were ultimately purchased by consumer class members, or reimbursed for by TPP class members. The true names, affiliations, and/or capacities of John Doe Wholesalers are not presently known. However, each John Doe proximately caused damages to Plaintiffs as alleged below, and each John Doe is liable to Plaintiffs for the acts and omissions alleged below as well as the resulting damages. Plaintiffs will amend this Master Class Complaint to allege the true names and capacities of the John Does when evidence reveals their identities.

F. True Names / John Doe Defendants 1-50

74. The true names, affiliations, and/or capacities, whether individual, corporate, partnership, associate, governmental, or otherwise, of John Does 1 through 50 are unknown to Plaintiffs at this time. Plaintiffs therefore sue these defendants using fictitious names. Each John Doe proximately caused damages to Plaintiffs as alleged below, and each John Doe is liable to Plaintiffs for the acts and omissions alleged below as well as the resulting damages. Plaintiffs will amend this Master Class Complaint to allege the true names and capacities of the John Does when evidence reveals their identities.

75. At all times relevant to this Master Class Complaint, each of the John Does was the agent, servant, employee, affiliate, and/or joint venturer of the other co-defendants and other John Does. Moreover, each Defendant and each John Doe acted in the full course, scope, and authority of that agency, service, employment, and/or joint venture.

[9] It is believed that three wholesalers comprise at least 90% of the wholesale drug market, and, likely were the entities that distributed adulterated, misbranded, and/or unapproved MCDs.

JURISDICTION AND VENUE

76. This Court has original jurisdiction pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d), because (a) at least one member of the proposed class is a citizen of a state different from that of Defendants, (b) the amount in controversy exceeds $5,000,000, exclusive of interest and costs, (c) the proposed class consists of more than 100 class members, and (d) none of the exceptions under the subsection apply to this action.

77. This Court has personal jurisdiction over Defendants, because Defendants have sufficient minimum contacts in New Jersey, and because Defendants have otherwise intentionally availed themselves of the markets within New Jersey through their business activities, such that the exercise of jurisdiction by this Court is proper and necessary.

78. Venue is proper in this District because Defendants reside in this District, "a substantial part of the events or omissions giving rise to the claim occurred" in this District, and, Defendants are subject to the personal jurisdiction of this Court. 28 U.S.C. § 1391(b)(3).

FACTUAL ALLEGATIONS

I. Background

A. Prescription Drug Reimbursement

79. The pharmaceutical supply chain in the United States consists of four major actors: pharmaceutical manufacturers, wholesale distributors, pharmacies, and Pharmacy Benefit Managers ("PBMs").

80. Pharmaceutical manufacturers produce drugs that they distribute to wholesale distributors, who further distribute to retail or mail-order pharmacies. Pharmacies dispense the prescription drugs to beneficiaries for consumption. Prescription drugs are processed through quality and utilization management screens by PBMs.

81. TPPs contract with and pay PBMs to administer their drug programs. PBMs, acting

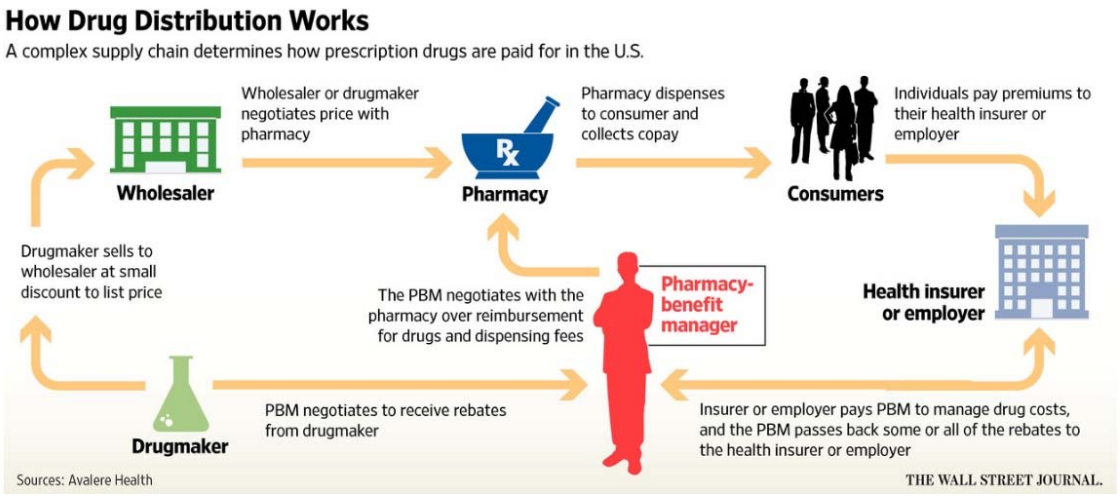
as agents for the TPPs, are tasked with developing drug formularies (the list of drugs included in coverage at various pricing "tiers"), processing claims, creating a network of retail pharmacies, and negotiating with pharmaceutical manufacturers. TPPs pay PBMs to control prescription drug costs. In some instances, PBMs are responsible for placing generic drugs, such as MCDs, on the TPPs' formularies.

82. In conducting formulary management, TPPs and their PBMs reasonably expect that generic prescription drugs reimbursable on their formularies are bioequivalent or otherwise the same as their RLD counterparts. TPPs seek to include the lowest cost generic drugs possible in their formularies. This is only made possible because of the manufacturers' and distributors' representations that these generic drugs, such as the Defendants' MCDs, comply with their respective ANDAs, which state that the generic drugs are bioequivalent to their respective branded drug. Thus, the TPPs permitted the MCDs to be included on their formularies based on the Defendants' misrepresentations that their MCDs were bioequivalent to brand-named Glucophage, complied with all current Good Manufacturing Practices ("cGMPs"), and were safe for consumption.

83. The formulary placement corresponds with the amount that a plan participant must contribute as a co-payment when purchasing a drug — the higher the placement, the lower the co-payment, and the higher likelihood that plan beneficiaries will purchase the drug instead of a more expensive alternative. As a result, higher formulary placement increases the likelihood that a doctor will prescribe the drug. TPPs provide copies of their PBMs' formularies to providers, pharmacists, and patients in their network to aid prescribers' adherence to the formulary.

84. The following chart, published by the Wall Street Journal, broadly illustrates the

pharmaceutical supply chain:[10]



85. When a patient presents his/her prescription at a pharmacy, the drug's placement on the TPP's formulary will determine the amount of the patient's co-payment. Once the patient's prescription is filled, the pharmacy submits a claim to the PBMs for reimbursement. PBMs then accumulate those individual reimbursements and present them to TPPs for payment.

B. The Generic Drug Approval Framework

86. The Drug Price Competition and Patent Term Restoration Act of 1984 – known as the Hatch-Waxman Act – is codified at 21 U.S.C. § 355(j).

87. The stated purpose of Hatch-Waxman is to strike a balance between rewarding genuine innovation and drug discovery by affording longer periods of brand drug marketing exclusivity while at the same time encouraging generic patent challenges and streamlining generic drug competition so that consumers gain the benefit of generic drugs at lower prices as quickly as possible.

[10] Joseph Walker, *Drugmakers Point Finger at Middlemen for Rising Drug Prices*, WALL ST. J. (Oct. 3, 2016), available at https://www.wsj.com/articles/drugmakers-point-finger-at-middlemen-for-rising-drug-prices-1475443336 (last accessed July 6, 2020).

88. Brand drug companies submitting a New Drug Application ("NDA") must demonstrate clinical safety and efficacy through well-designed clinical trials. 21 U.S.C. § 355 *et seq.*

89. By contrast, generic drug companies submit an ANDA. Rather than demonstrate clinical safety and efficacy, generic drug companies need only demonstrate bioequivalence to the brand or reference listed drug ("RLD"). Bioequivalence is the "absence of significant difference" in the pharmacokinetic profiles of two pharmaceutical products. 21 C.F.R. § 320.1(e).

1. *ANDA Applications Must Demonstrate Bioequivalence*

90. The bioequivalence basis for ANDA approval is premised on the generally accepted proposition that equivalence of pharmacokinetic profiles of two drug products is evidence of therapeutic equivalence. In other words, if (1) the RLD is proven to be safe and effective for the approved indication through well-designed clinical studies accepted by the FDA, and (2) the generic company has shown that its ANDA product is bioequivalent to the RLD, then (3) the generic ANDA product must be safe and effective for the same approved indication as the RLD.

91. As part of its showing of bioequivalence under 21 C.F.R. § 314.50(d), the ANDA must also contain specific information establishing the drug's stability, including:

- a full description of the drug's substance, including its physical and chemical characteristics and stability; and
- the specifications necessary to ensure the identity strength, quality and purity of the drug substance and the bioavailability of the drug products made from the substance, including, for example, tests, analytical procedures, and acceptance criteria relating to stability.

92. Generic drug manufacturers have an ongoing federal duty of sameness in their

products. Under 21 U.S.C. § 355(j), the generic manufacturer must show the following things as relevant here: the active ingredient(s) are the same as the RLD, § 355(j)(2)(A)(ii); and, that the generic drug is "bioequivalent" to the RLD and "can be expected to have the same therapeutic effect," *id.* at (A)(iv). A generic manufacturer (like a brand manufacturer) must also make "a full statement of the composition of such drug" to the FDA. *Id.* at (A)(vi); *see also* § 355(b)(1)(C).

93. A generic manufacturer must also submit information to show that the "labeling proposed for the new drug is the same as the labeling approved for the [RLD][.]" 21 U.S.C. § 355(j)(2)(A)(v).

2. *ANDA Applications Must Provide Information About the Manufacturing Plants and Processes*

94. The ANDA application must also include information about the manufacturing facilities of the product, including the name and full address of the facilities, contact information for an agent of the facilities, and the function and responsibility of the facilities.

95. The ANDA application must include a description of the manufacturing process and facility and the manufacturing process flow chart showing that there are adequate controls to ensure the reliability of the process.

96. Furthermore, the ANDA application must contain information about the manufacturing facility's validation process, which ensures that the manufacturing process produces a dosage that meets product specifications.

3. *ANDA Applications Must Comply with cGMPs*

97. Additionally, ANDA applications must include certain representations related to compliance with cGMPS.

98. The ANDA application must contain cGMP certifications for both the ANDA applicant itself, and also the drug product manufacturer (if they are different entities).

4. *ANDA Approval is Contingent upon Continuing Compliance with ANDA Representations of Sameness*

99. Upon granting final approval for a generic drug, the FDA will typically state that the generic drug is "therapeutically equivalent" to the branded drug. The FDA codes generic drugs as "A/B rated" to the RLD[11] branded drug. Pharmacists, physicians, and patients can expect such generic drugs to be therapeutically interchangeable with the RLD, and generic manufacturers expressly warrant by including same labeling as the RLD delivered to consumers in each prescription of its generic products. Further, by simply marketing generic drugs pursuant to the brand-name drug's label under the generic name (e.g., metformin or metformin HCL), generic manufacturers impliedly warrant that the generic drug is therapeutically equivalent to the brand-name drug.

100. If a generic drug manufacturer ceases to manufacture a drug that meets all terms of its ANDA approval, or in other words, when the drug is not the same as its corresponding brand-name drug, then the manufacturer has created an entirely new and unapproved drug.

101. If a generic drug manufacturer ceases to manufacture a drug that meets all terms of its ANDA approval, or in other words, when the drug is not the same as its corresponding brand-name drug, the generic manufacturer may no longer rely on the brand-name drug's labeling.

102. According to the FDA, there are in excess of fifty (50) approved ANDAs for Metformin Hydrochloride (the generic versions of the RLDs Glucophage and Glucophage XR).

[11] The FDA's Drug Glossary defines an RLD as follows: "A Reference Listed Drug (RLD) is an approved drug product to which new generic versions are compared to show that they are bioequivalent. A drug company seeking approval to market a generic equivalent must refer to the Reference Listed Drug in its Abbreviated New Drug Application (ANDA). By designating a single reference listed drug as the standard to which all generic versions must be shown to be bioequivalent, FDA hopes to avoid possible significant variations among generic drugs and their brand name counterpart."

C. Approval of ANDAs Related to Metformin Hydrochloride

103. Metformin was first discovered in 1922, and first marketed in the United States in 1995. Metformin is regarded as so critical to diabetes management that it is listed by the WHO on the WHO's List of Essential Medicines.

104. In 2016, Metformin was the fourth-most prescribed medicine in the United States, with more than 81 million prescriptions dispensed.

105. The RLDs for Metformin Hydrochloride are Glucophage and Glucophage XR.

106. Glucophage and Glucophage XR were first approved by the FDA in 1995 and 2000, respectively, and marketed by EMD Serono Inc. EMD Serono was later acquired by Merck KGaA around 2006 and branded as Merck Serono with a focus on biopharmaceuticals.

107. Generic approvals of Metformin Hydrochloride began occurring in the early 2000s after the expiration of Glucophage's exclusivity period.

108. Glucophage and Glucophage XR's FDA-approved labels specify the active and inactive ingredients. NDMA nor any other nitrsosamine is listed among the FDA-approved ingredients nor are any of these contaminants FDA-approved ingredients of any generic metformin-containing product approved pursuant to an ANDA.

109. Almost immediately after FDA approval of Glucophage and Glucophage XR, generic companies began filing ANDAs to secure approval to market generic Metformin Hydrochloride products. The first generic Metformin Hydrochloride products secured approval in early 2002.

D. Drugs Must Be Manufactured in Compliance with Good Manufacturing Practices

110. Under federal law, pharmaceutical drugs must be manufactured in accordance with "current Good Manufacturing Practices" ("cGMPs") to ensure they meet safety, quality, purity,

identity, and strength standards. *See* 21 U.S.C. § 351(a)(2)(B).

111. 21 C.F.R. § 210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." In other words, entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

112. The FDA's cGMP regulations are found in 21 C.F.R. Parts 210 and 211. These detailed regulations set forth minimum standards for: organization and personnel (Subpart B); buildings and facilities (Subpart C); equipment (Subpart D); control of components and drug product containers and closures (Subpart E); production and process controls (Subpart F); packaging and label controls (Subpart G); holding and distribution (Subpart H); laboratory controls (Subpart I); records and reports (Subpart J); and returned and salvaged drug products (Subpart K). The FDA has worldwide jurisdiction to enforce these regulations if the facility is making drugs intended to be distributed in the United States.

113. Any drug not manufactured in accordance with cGMPs is deemed "adulterated and/or misbranded" or "misbranded" and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). States have enacted laws adopting or mirroring these federal standards.

114. Under federal law, cGMPs include "the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products." 21 U.S.C. § 351(j). Accordingly, it is a cGMP violation for a manufacturer to contract

out prescription drug manufacturing without sufficiently ensuring the continuing quality of the subcontractors' operations.

115. FDA regulations require a "quality control unit" to independently test drug product manufactured by another company on contract:

> There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company. 21 C.F.R. § 211.22(a).

116. Indeed, FDA regulations require a drug manufacturer to have "written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." 21 C.F.R. § 211.100.

117. A drug manufacturer's "[l]aboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity." 21 C.F.R. § 211.160.

118. "Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays" and a "statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested." 21 C.F.R. § 211.194.

E. Adulterated or Misbranded Drugs Are Illegal to Sell

119. Under federal law, pharmaceutical drugs must be manufactured in accordance with cGMPs to ensure they meet safety, quality, purity, identity, and strength standards. *See* 21 U.S.C. § 351(a)(2)(B).

120. 21 C.F.R. § 210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." In other words, entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

121. The FDA's cGMP regulations are found in 21 C.F.R. Parts 210 and 211. These detailed regulations set forth minimum standards regarding: organization and personnel (Subpart B); buildings and facilities (Subpart C); equipment (Subpart D); control of components and drug product containers and closures (Subpart E); production and process controls (Subpart F); packaging and label controls (Subpart G); holding and distribution (Subpart H); laboratory controls (Subpart I); records and reports (Subpart J); and returned and salvaged drug products (Subpart K). The FDA has worldwide jurisdiction to enforce these regulations if the facility is making drugs intended to be distributed in the United States.

122. Any drug not manufactured in accordance with cGMPs is deemed "adulterated and/or misbranded" or "misbranded" and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). States have enacted laws adopting or mirroring these federal standards.

123. Among the ways a drug may be adulterated and/or misbranded are:

a. "if it has been prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health"[12] ;

b. "if . . . the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements … as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess"[13] ;

c. "If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and … its quality or purity falls below, the standard set forth in such compendium. …"[14]; and/or

d. "If . . . any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor."[15]

124. A drug is misbranded:

a. "If its labeling is false or misleading in any particular"[16];

b. "If any word, statement, or other information required…to appear on the label or labeling is not prominently placed thereon…in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use"[17];

c. If the labeling does not contain, among other things, "the proportion of each active ingredient…"[18];

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[12] 21 U.S.C. § 351(a)(2)(A).
[13] 21 U.S.C. § 351(a)(2)(B).
[14] 21 U.S.C. § 351(b).
[15] 21 U.S.C. § 351(d).
[16] 21 U.S.C. § 352(a)(1).
[17] 21 U.S.C. § 352(c).
[18] 21 U.S.C. § 352(e)(1)(A)(ii)

d. "Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings … against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users. …"[19];

e. "If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein."[20]

f. "if it is an imitation of another drug"[21];

g. "if it is offered for sale under the name of another drug"[22];

h. "If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof"[23];

i. If the drug is advertised incorrectly in any manner[24]; and/or

j. If the drug's "packaging or labeling is in violation of an applicable regulation…"[25]

125. The manufacture and sale of any adulterated or misbranded drug is prohibited under federal law.[26]

126. The introduction into commerce of any adulterated or misbranded drug is also prohibited.[27]

127. Similarly, the receipt in interstate commerce of any adulterated or misbranded or misbranded drug is also unlawful.[28]

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[19] 21 U.S.C. § 352(f).
[20] 21 U.S.C. § 352(g).
[21] 21 U.S.C. § 352(i)(2).
[22] 21 U.S.C. § 352(i)(3).
[23] 21 U.S.C. § 352(j).
[24] 21 U.S.C. § 352(n).
[25] 21 U.S.C. § 352(p).
[26] 21 U.S.C. § 331(g).
[27] 21 U.S.C. § 331(a).
[28] 21 U.S.C. § 331(c).

128. As articulated in this Complaint, Defendants' unapproved MCD drugs were adulterated and/or misbranded in violation of all of the above-cited reasons.

129. Plaintiffs reference federal law in this Complaint not in any attempt to enforce it, but to demonstrate that their state-law tort claims do not impose any additional obligations on Defendants, beyond what is already required of them under federal law.

II. The Drugs Purchased by Plaintiffs Were Not Metformin, But Adulterated and Misbranded Drugs, Not of the Same Quality

130. The FDA's website provides the definition for a drug:

> The Federal Food Drug and Cosmetic Act (FD&C Act) and FDA regulations define the term drug, in part, by reference to its intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." Therefore, almost any ingested or topical or injectable product that, through its label or labeling (including internet websites, promotional pamphlets, and other marketing material), is claimed to be beneficial for such uses will be regulated by FDA as a drug. The definition also includes components of drugs, such as active pharmaceutical ingredients.[29]

131. 21 C.F.R. § 210.3(b)(7) defines an "active ingredient" in a drug as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect."[30]

132. NDMA and other nitrosamines can cause cancer by triggering genetic mutations in

[29] https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/RegulatedProducts/ucm511482.htm#drug.
[30] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=210.3.

humans. This mutation affects the structure of the human body, and thus, NDMA is, by definition, an active ingredient in a drug.

133. FDA also requires that whenever a new active ingredient is added to a drug, the drug becomes a new drug, requiring submission of a New Drug Application by the manufacturer. Absent such an application, followed by a review and approval by the FDA, this new drug remains a distinct, unapproved product.[31]

134. This new and unapproved drug with additional active ingredients (such as nitrosamines in the subject MCDs) cannot have the same label as the brand-name drug, as the two products are no longer the same.

135. At the very least and alternatively, drugs with different and dangerous ingredients than their brand-name counterparts are adulterated or misbranded under federal law, and the sale or introduction into commerce of adulterated or misbranded drugs is illegal.[32]

136. Because the MCDs ingested by Plaintiffs were never approved or even reviewed by the FDA, the FDA never conducted an assessment of safety or effectiveness for these drugs.

137. The presence of additional active ingredients (NDMA), and potentially other deviations from Defendants' ANDA approvals rendered Defendants' MCDs of a lesser quality than FDA-approved generic MCDs or their RLDs.

138. Plaintiffs reference federal law in this Complaint not in any attempt to enforce it, but to demonstrate that their state-law tort claims do not impose any additional obligations on Defendants, beyond what is already required of them under federal law.

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[31] *See* 21 C.F.R. § 310.3(h).

[32] *See generally* https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false (last accessed July 6, 2020).

III. Defendants Made False Statements in the Labeling of its MCDs

139. A manufacturer must give adequate directions for the use of a pharmaceutical drug so that a "layman can use a drug safely and for the purposes for which it is intended,"[33] and conform to requirements governing the appearance of the label.[34]

140. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device,[35] and therefore broadly includes nearly every form of promotional activity, including not only "package inserts" but also advertising.

141. "Most, if not all, labeling is advertising. The term 'labeling' is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."[36]

142. If a manufacturer labels a drug but omits ingredients, that renders the drug misbranded.[37]

143. Because Defendants did not disclose that their MCDs contained NDMA and/or NDEA as ingredients, the subject drugs were misbranded.

144. In addition, by referring to their drugs as "metformin" or "metformin HCL" or "metformin ER" Defendants were making false statements regarding their MCDs.

145. It is unlawful to introduce a misbranded drug into interstate commerce.[38] Thus, the MCDs ingested by individual Plaintiffs were unlawfully distributed and sold.

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[33] 21 C.F.R. § 201.5.
[34] 21 C.F.R. § 801.15.
[35] *Id.* 65 Fed. Reg. 14286 (March 16, 2000).
[36] *U.S. v. Research Labs.*, 126 F.2d 42, 45 (9th Cir. 1942).
[37] 21 C.F.R. § 201.6; 201.10.
[38] 21 U.S.C. § 331(a).

IV. Defendants Represented MCDs were Manufactured in Compliance with Current Good Manufacturing Practices

146. Under federal law, pharmaceutical drugs must be manufactured in accordance with "current Good Manufacturing Practices" ("cGMPs") to ensure they meet safety, quality, purity, identity, and strength standards. *See* 21 U.S.C. § 351(a)(2)(B).

147. 21 C.F.R. § 210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." In other words, entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

148. The FDA's cGMP regulations are found in 21 C.F.R. Parts 210 and 211. These detailed regulations set forth minimum standards for: organization and personnel (Subpart B); buildings and facilities (Subpart C); equipment (Subpart D); control of components and drug product containers and closures (Subpart E); production and process controls (Subpart F); packaging and label controls (Subpart G); holding and distribution (Subpart H); laboratory controls (Subpart I); records and reports (Subpart J); and returned and salvaged drug products (Subpart K). The FDA has worldwide jurisdiction to enforce these regulations if the facility is making drugs intended to be distributed in the United States.

149. Any drug not manufactured in accordance with cGMPs is deemed "adulterated and/or misbranded" or "misbranded" and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). States have enacted laws adopting or mirroring these federal standards.

150. Under federal law, cGMPs include "the implementation of oversight and controls

over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products." 21 U.S.C. § 351(j). Accordingly, it is a cGMP violation for a manufacturer to contract out prescription drug manufacturing without sufficiently ensuring the continuing quality of the subcontractors' operations.

151. FDA regulations require a "quality control unit" to independently test drug product manufactured by another company on contract:

> There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company. 21 C.F.R. § 211.22(a).

152. Indeed, FDA regulations require a drug manufacturer to have "written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." 21 C.F.R. § 211.100.

153. A drug manufacturer's "[l]aboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity." 21 C.F.R. § 211.160.

154. "Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays" and a "statement of the results of tests and how the results compare with established

standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested." 21 C.F.R. § 211.194.

V. Defendants Were Actively Violating cGMPs in Their Foreign Manufacturing Facilities

155. For some time, Defendants have known that generic drugs manufactured overseas, particularly in China and India, were found or suspected to be less safe and effective than their branded equivalents or domestically made generics because of grossly inadequate manufacturing processes, procedures and compliance with cGMPs.

156. Defendants' foreign manufacturing operations at issue were no exception to these systemic quality failures.

A. Actavis/Teva's Inadequate Manufacturing Processes

157. As noted in the Valisure Citizen's Petition, "the presence of NDMA in metformin products may be primarily due to contamination during manufacturing." Teva and its related subsidiaries and affiliates have been the subject of extensive FDA investigations revealing its seriously flawed and unreliable manufacturing practices and a history of recurring and ongoing cGMP violations.

158. On February 1, 2019 the FDA issued a Warning Letter (Case #567857) to Teva subsidiary and Actavis affiliate, Actavis Laboratories FL, Inc., based on its July 9 to 19, 2018 inspection of a Davie, Florida facility.[39] The Warning Letter summarizes "significant violations" of cGMP regulations for finished pharmaceuticals in violation of 21 C.F.R., Parts 210 and 211, including but not limited to failing to establish an adequate control unit with the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging materials, labeling and drug products in violation of 21 C.F.R. § 211.22(a). More specifically, the FDA found that

[39] FDA, *Actavis Laboratories FL, Inc.*, (Feb. 1, 2019), *available at*: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/actavis-laboratories-fl-inc-567857-02012019.

the Teva-affiliated facility lacked "an adequate ongoing program for monitoring process controls to ensure stable manufacturing operations and consistent drug quality."[40]

159. In connection with its investigation, on July 19, 2018, the FDA issued a Form 483 detailing the grossly inadequate procedures and cGMP violations relating specifically to the manufacturing of MCDs, which included: not fully following responsibilities and procedures applicable to the quality control unit (e.g., failing to detect deficiencies in operations and failing to implement adequate corrective and preventative action to ensure its products are manufactured in accordance with cGMPs and meet specifications); failing to establish control procedures and monitor manufacturing processes "that may be responsible for causing variability in the characteristics of in-process material and the drug product"; and not cleaning equipment and utensils at appropriate intervals "to prevent malfunctions that would alter the safety, identity, strength, quality or purity of the drug product."[41]

160. This was not Defendants' first warning regarding the deficiencies in its MCD manufacturing. The FDA's Warning Letter references similar cGMP observations found during previous FDA inspections in December 2013, January 2016 and November 2017, noting: "[t]hese repeated failures demonstrate that executive management oversight and control over the manufacture of drugs is inadequate."[42]

161. In March 2014, Teva issued a Class II recall for 500mg metformin tablets because of cGMP deviations where laboratory testing was not following cGMP requirements.

162. In 2016, the FDA required post-market sampling and testing for certain drugs to compare "high risk solid oral generic products made by India and non-India firms," including Teva's

[40] *Id.*
[41] FDA Form 483, *Actavis Laboratories FL, Inc.*, (July 19, 2018).
[42] *Id.*

metformin extended release tablets.[43]

163. A few years later, an FDA "For Cause" inspection of Teva affiliate from April 8 to 16, 2019 was initiated to investigate APIs "that are implicated for potential contamination with carcinogenic and mutagenic impurities" and distributed in the U.S.[44] After the inspection, Teva was issued an FDA Form 483 for "[i]nadequate risk assessment by the quality unit" for failing to "evaluate all potential root causes for contamination of [] APIs" and failing to "follow the responsibilities and procedures applicable to quality control unit."[45]

164. The FDA found Teva "did not thoroughly assess [key starting materials] KSMs for the potential contamination of genotoxic and suspected human carcinogenic. . .derivatives. . .and other. . .impurities," despite knowingly receiving multiple KSMs for APIs from a manufacturer of KSMs with processes identified as having a "high risk of forming. . . impurities."[46] Even after detecting an impurity in February 2019, Teva failed to develop a formal process to assess KSMs for impurities. Teva did not take, test or consider any samples of KSMs, but chose to conduct a wholly inappropriate "theoretical evaluation" of KSMs to detect impurity pathways.

165. Teva also failed to re-assess its cleaning validation program of non-dedicated equipment. During its inspection, the FDA discovered unwrapped production equipment stored outside with "what appeared to be bird feces," in a manner wholly inadequate to "prevent contamination or carry-over material that would alter the quality of the intermediate or API beyond. . .official or other established specifications."[47]

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[43] *See* FDA, *Drug Quality: Postmarketing Sampling and Testing Results for Drugs (FY 2016)*, https://www.fda.gov/media/103635/download.
[44] FDA Establishment Inspection Report, *Teva API India Pvt. Ltd.*, (April 8-16, 2019).
[45] *Id*.
[46] FDA Form 483, *Teva API India Pvt. Ltd.*, (April 16, 2019).
[47] *Id*.

166. Teva is responsible for developing its manufacturing processes, maintaining appropriate controls and standard operating procedures, and implementing suitable analytical methods to detect and prevent potential impurities like NDMA. Rather than protect against the possible formation of mutagenic impurities in its metformin manufacturing processes, Teva's repeated violations of cGMPs and utter lack of disregard for quality control and assurance measures encouraged the proliferation of NDMA and did not provide the proper assurances that Teva's MCDs met the requirements of the Food and Drug Cosmetics Safety Act and has the identity and strength, and/or met the quality and purity characteristics, which Teva's MCDs purported to represent. As a result, Teva willfully and recklessly introduced contaminated, adulterated and/or misbranded metformin containing products into the U.S. market.

B. Emcure/Granules/Heritage's Inadequate Manufacturing Processes

167. The named Granules defendants above are wholly owned subsidiaries of Granules India Ltd, and have API manufacturing facilities in India.

168. Granules manufactures metformin API at these facilities for import to the U.S. market, and thus have quality assurance obligations with respect to Granules' processes, APIs, and finished products as set forth above pursuant to federal law.

169. As demonstrated below, Emcure, Granules and Heritage have a truly abysmal history of deviations from the FDA's cGMP standards, along with an embedded culture of disregard for U.S. law and regulations.

170. For starters, Heritage's former CEO, Jeffrey A. Glazer, and one of its Senior Vice Presidents, Jason T. Malek, recently pleaded guilty to price-fixing generic drugs, and agreed to cooperate with federal prosecutors.

171. Emcure, Granules and Heritage's cGMP track record is one of repeated failure.

172. Emcure has been inspected 12 times since 2009, the most recent inspection (in February

20, 2019), resulting in a Warning Letter from the FDA, its most forceful rebuke.

173. In the Warning Letter, the FDA reprimanded Emcure for its failure to "adequately investigate" failures in sterility, and failed to investigate the root cause of bacterial growth in their drug products.[48]

174. At an inspection of Emcure's API manufacturing facility two months earlier, in December of 2018, the FDA chided Emcure for a failure to "validate or verify all analytical methods" to be used for the "release of raw materials" for use in manufacturing.

175. After a September 10-12, 2012 inspection of Granules' Qutbullapar Mandal, Ranga Reddy District-based facility, the FDA informed Granules that it was not testing API upon receipt for identification and quality assurance purposes. Instead, Granules was only conducting visual inspection of API, which does not meet Granules' cGMP obligations.

176. In 2015, Heritage received an FDA 483 and a formal warning letter regarding Heritage's failure to report adverse events.

177. On December 5-9, 2016, the FDA inspected Grandules' API manufacturing facility in Visakhapatnam, Andhra Pradesh, India. Among other cGMP failures identified by the FDA, the FDA inspectors informed Granules of several quality-related issues related to the API plant where metformin API is manufactured.

178. First, Granules was not reviewing deviations and including such reports in their batch records. The FDA inspector identified at least 21 instances in which batches did not have a deviation remarks report attached or repeated numbering the same. Thus, batches of API were being released without full investigation into potential deviations.

[48] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emcure-pharmaceuticals-limited-576961-08022019 (last accessed June 30, 2020).

179. This resulted in production master batch records being incomplete and, according to the FDA, missing information relating to deviations, additional operations, comments, observations, and sampling.

180. The FDA also found that Granules laboratory control records did not include complete data derived from tests to ensure compliance with those tests' specifications and standards, including examinations and assays.

181. Moreover, the FDA found that Granules had made changes to its API manufacturing processes without justification in some instances.

182. After a series of inspections from January to February 2018 of Heritage's East Brunswick, New Jersey facility, the FDA informed Heritage of several cGMP failures relating to quality assurance.

183. For starters, the FDA observed that Heritage's laboratory controls lacked the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

184. The FDA also found that Heritage had not established control procedures to monitor and validate the manufacturing processes that caused deviations and variability in drug product and in-process material.

185. Additionally, the FDA found that Heritage was not documenting monitoring and control methods and data from Heritage's process equipment. This prevented there being a "verifiable record of production for each lot of drug product" according to FDA inspectors.

186. Importantly, the FDA also found that Heritage's electronic data was not adequately controlled to prevent alteration or deletion. The FDA stated that "quality unit procedures for control of records generated electronically are inadequate."

187. Just a month later, in March 2018, FDA inspectors conducted an inspection of Granules'

Hyderabad, India-based finished dose manufacturing facilities.

188. The FDA found that Granules' "API specifications lack[ed] adequate acceptance criteria."

189. In July 2019, FDA inspectors visited Granules' "drug substance" manufacturing facilities in Bonthapally Village Gummadidala Mandal, Sangareddy, Telangana, India. The FDA inspectors found that Granules did not investigate or resolve fully complaints related to drug substance quality, and cited an instance where a Granules customer reported failing assay and bulk density results for batches of Granules drug product. Granules closed out the complaint without investigating the cause of the failing assay and bulk density results.

C. Amneal/AvKare's Inadequate Manufacturing Processes

190. Amneal has API manufacturing facilities located in Matoda, Gujarat, India, and Piscataway, New Jersey, and Hauppauge, New York.

191. Amneal manufactures MCDs at these and/or other facilities for the U.S. market, and the Amneal Defendants thus have quality assurance obligations with respect to Amneal's processes and finished products as set forth above pursuant to federal law.

192. Amneal's problematic manufacturing practices were first noted by the FDA as early as 2003, when the FDA cited Amneal because "[t]he assay method of testing stability samples has not been shown to be stability-indicating in that the firm has not demonstrated peak purity for the active peak."

193. This inspection would only be the first of such damning inspections conducted by the FDA from 2003 to present. In fact, Amneal's facilities were inspected an astounding 94 times in this time period.

194. In November 2009, at Amneal's Hauppauge, New York facilities, the FDA found quality assurance problems related to Amneal's quality control unit, specifically concerning finished

dose packaging.

195. During one of these most recent inspections in April 2018 of one of Amneal's Indian manufacturing facilities, located in Matoda, Gujarat, India, Amneal was cited for not reviewing, or even requesting to review, raw data from testing outsourced by Amneal to third-party vendors.

196. Concomitantly to this inspection in India, the FDA also inspected Amneal's Piscataway, N.J. manufacturing facility, and found that Amneal failed to appropriately maintain or create written records of investigations into unexplained discrepancies.

197. During a February 2019 inspection, Amneal's Branchburg, NJ manufacturing facility was cited for failure to thoroughly review unexplained discrepancies, and failures of batches to meet set specifications, as well as failure to test all materials provided by component suppliers to validated the information provided by the suppliers.

D. Aurobindo's Inadequate Manufacturing Processes

198. Aurobindo has API manufacturing facilities located in Hyderabad, Telangana, India.

199. Aurobindo manufactures MCDs for each Aurobindo Defendant at these facilities, and Aurobindo Defendants thus have quality assurance obligations with respect to Aurobindo's processes and finished products as set forth above pursuant to federal law.

200. Aurobindo and its related subsidiaries and affiliates have been the subject of extensive FDA investigations revealing its seriously flawed and unreliable manufacturing practices and a history of recurring and ongoing cGMP violations.

201. Aurobindo has a history of deviations from the FDA's cGMP standards.

202. After an inspection of a Hyderabad facility from June 27 to July 1, 2016, the FDA told Aurobindo that its "[i]nvestigations are inadequate." The FDA explained that Aurobindo failed to initiate stability testing, and "[t]he deviation record contains field 'Number of previous deviations in this product/system.' This field requires previous deviations of the same product or deviation

type to be reported, no previous deviations were reported in this field." Moreover, "[t]his is a repeat observation from the 2014 inspection."

203. Three months later, the FDA returned to Aurobindo's Hyderabad facilities and found four noteworthy manufacturing problems. First, "[a]n [redacted] Field Alert was not submitted within three working days of receipt of information concerning significant chemical, physical, or other change or deterioration in a distributed drug product." Second, "[l]aboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that conform [sic] to appropriate standards of identity, strength, quality and purity." Third, "[t]here are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." Fourth, the "use of instruments and recording devices not meeting establishes specifications was observed."

204. In October 2016, the FDA observed that Aurobindo's nearby Borpatla facility had inadequately validated equipment cleaning procedures.

205. In April 2017, the FDA observed that the manufacturing equipment in Aurobindo's Hyderabad facilities "is not always maintained to achieve its intended purposes." "Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components and drug products conform to appropriate standards of identity, strength, quality and purity." "Changes to written procedures are not drafted, reviewed and approved by the appropriate organizational unit." "[C]orrective and preventative actions (CAPAs), identified and initiated because of out of specifications (OOS) laboratory investigations, do not correlate to the identified root cause. In certain cases, CAPAs are not initiated at all." "Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate

design to facilitate operations for its intended use." "Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel." "Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established."

206. Four months later, the FDA reiterated that "[t]here are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." Second, "[c]ontrol procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product."

207. In February 2018, the FDA made nine more disturbing observations at Aurobindo's Hyderabad facilities. First, "[a]septic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions." Second, "[e]quipment and utensils are not cleaned, maintained and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product." Third, "[e]quipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use." Fourth, "[b]uildings used in manufacture, processing, packing or holding of drug products are not free of infestation by rodents, birds[,] insects, and other vermin." Fifth, "[p]rocedures for the cleaning and maintenance of equipment are deficient regarding sufficient detail of the methods, equipment, and materials used in the cleaning and maintenance operation, and the methods of disassembly and reassembling equipment as necessary to assure proper cleaning and maintenance." Sixth, "[e]mployees engaged in the manufacture, processing, packing and holding of a drug product lack the training required to

perform their assigned functions." Seventh, the "statistical quality control criteria fail to include appropriate acceptance levels and rejection levels." Eighth, "[e]stablished laboratory control mechanisms are not followed and documented at the time of performance." Lastly, "[a]ppropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel."

208. It is clear Aurobindo has made no efforts to correct any of these errors and continues to engage in grossly inadequate manufacturing processes. During an inspection *only last year* (May 2019), an investigator made note of a panoply of serious issues which continue to call the integrity of the API manufacturing operations into question.

209. For example, in determining that the Medchal, Telangaga facility was not following quality control measures, and likewise did not have quality control procedures in place, the investigator observed "loose handwritten notebooks with what appears to be laboratory test data results."

210. Additionally, while Aurobindo claimed to have performed tests and quality control activities on API as a result of the FDA's investigation into adulterated drug products, during the inspection, the investigator found that the API was not being adequately retained and/or appropriately identified, calling Aurobindo's testing of this API into question. More troubling, the API sampled and analyzed by the investigator was to set to be shipped into the United States.

211. The investigator also found a slew of data integrity issues. The investigator observed "multiple sequences where interrupted sample injections were injected and showed that the sample did not run, shown on the chromatogram as "incomplete data." The testing systems also allowed certain employees to "verify incomplete data in raw data file." The investigator found that the quality control reviewers attested to practices which "contradict actual review practices performed

by reviews." Were these baseline data issues not enough, the investigator also noted that the facility did not retain adequate backup of the data, other than the assorted loose notebooks found lying around the facility.

212. The investigator also noted that on top of all of the gross processing and data integrity issues, *even the building itself* did not have the "suitable construction to facility cleaning, maintenance and proper operations." The investigator noted that in a stability sample storage room, they observed a "PVC pipe connected to an air conditioner unit on one end, and paced in a blue plastic bucket on the other end with approximate 50% of the bucket filled with condensate water." There were four similar setups in other critical rooms in the facility.

E. Alkem/Ascend's Inadequate Manufacturing Processes

213. Defendants Alkem and Ascend have manufacturing facilities in India and the United States, and have a repeat offender track record of cGMP violations.

214. In September 2016, the FDA inspected Alkem's Daman, India-based manufacturing facilities and found a litany of cGMP violations related to quality assurance.

215. First, the FDA inspectors found that Alkem's "[l]aboratory records do not include complete data derived from all tests, examinations and assay necessary to ensure compliance with established specifications and standards." Specifically, the FDA found that the quality control unit did not report all test results from out-of-specification ("OOS") investigations. The FDA also found that Alkem re-tested OOS results.

216. The FDA also found that Alkem was grossly deficient in ensuring the stability of its drug products. The FDA Alkem's "[l]aboratory controls do not include the establishment of scientifically sound and appropriate specifications and sampling plans designed to assure that components, in-process materials and drug products conform to appropriate standards of identity,

strength, quality and purity."

217. In addition, the FDA found that Alkem often deviated written process and production control procedures in ways that were not justifiable.

218. Furthermore, the FDA found that Alkem violated its cGMP obligations because its distribution system was "deficient in that each lot of drug product cannot be readily determined to facilitate its recall if necessary." Similarly, procedures describing the warehousing of drug products were not established or followed by Alkem.

219. And finally, to top it all off, the FDA found that Alkem's quality control unit (required by FDA cGMP regulations) had not established an effective system for managing the quality of Alkem's drug products, including even the most basic quality control unit functions of having written responsibilities and procedures for the unit.

220. In essence, the FDA found that Alkem's quality control was non-existent.

221. In September 2017, the FDA inspected Alkem's Solan, India-based manufacturing facilities and found similar gross cGMP deficiencies.

222. Specifically, the FDA remarked that there were "no written procedures for production and process controls designed to assure drug products the identity, strength, quality and purity they purport or are represented to possess."

223. The FDA also found that the quality control unit had not established full audit trails for sampling drug products, which prevented "meaningful review of the [sampling] instrument history" (i.e., to detect the manipulation or deletion of sampling data).

224. The FDA again visited Alkem's Daman, India-based manufacturing facilities in March 2018.

225. The FDA's first written observation was: "There is no quality control unit." In all

caps and starred, the FDA inspectors wrote, "***THIS IS A REPEAT OBSERVATION***" and also noted discrepancies and abnormalities in Alkem's sampling data and methods.

226. Among other observations of gross cGMP failures, the FDA found that Alkem's employees "lack[ed] the training and experience required to perform their assigned functions."

227. In May 2019, FDA inspectors visited Alkem's Baddi, Himachal Pradesh, India manufacturing facilities. The observations are like those observed by FDA inspectors at Alkem's other facilities.

228. The FDA found that Alkem's quality control unit lacked the responsibility and authority to approve/reject all drug products. Specifically, the FDA found that Alkem had a "practice of sending quarantine drug products to their U.S. distribution company [Ascend]. A disposition decision is not made until after shipment … [which] takes [the drug products] outside the firm's quality system direct control."

229. The FDA found other quality control failures as well as failures to confirm the adequacy of in-process materials.

230. In February 2020, the FDA again visited Alkem's Baddi, Himachal Pradesh, India manufacturing facilities.

231. Again, the FDA found cGMP failures including the failure to investigate the failure of a batch when it or its components did not meet specifications.

VI. Defendants' Action Resulted in Adulterated and Misbranded MCDs Contaminated with NDMA

A. The Nitrosamine Contaminant ("NDMA")

232. N-nitrosodimethylamine, commonly known as NDMA, is an odorless, yellow

liquid.[49]

233. According to the U.S. Environmental Protection Agency, "NDMA is a semivolatile chemical that forms in both industrial and natural processes."[50]

234. NDMA can be unintentionally produced in and released from industrial sources through chemical reactions involving other chemicals called alkylamines.

235. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.[51]

236. The U.S. Department of Health and Human Services (DHHS) similarly states that NDMA is reasonably anticipated to be a human carcinogen.[52] This classification is based upon DHHS's findings that NDMA caused tumors in numerous species of experimental animals, at several different tissue sites, and by several routes of exposure, with tumors occurring primarily in the liver, respiratory tract, kidney, and blood vessels.[53]

237. According to the Agency for Toxic Substances and Disease Registry, "NDMA is very harmful to the liver of humans and animals. People who were intentionally poisoned on one or several occasions with unknown levels of NDMA in beverage or food died of severe liver damage accompanied by internal bleeding."[54]

238. WHO and IARC classify NDMA as one of sixty-six agents that are "probably

[49] https://www.atsdr.cdc.gov/toxprofiles/tp141.pdf.
[50] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[51] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[52] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[53] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[54] https://www.atsdr.cdc.gov/toxprofiles/tp141.pdf, p. 2.

carcinogenic to humans" (Classification 2A).

239. Anecdotally, NDMA has also been used in intentional poisonings.[55]

B. Formation of NDMA and/or NDEA in Defendants' Adulterated, Misbranded, and/or Unapproved MCDs

240. NDMA is considered a genotoxic compound, as it contains nitroso groups, which are gene-mutating groups.[56]

241. The pharmaceutical industry has been aware of the potential for the formation of nitrosamines in pharmaceutical drugs at least as far back as 2005, or earlier.[57]

C. The Valisure Citizen Petition

242. Valisure is an online pharmacy licensed in thirty eight (38) states and also an analytical laboratory accredited by the International Organization for Standardization ("ISO"). Valisure is registered with the Drug Enforcement Administration (Pharmacy: FV7431137, Laboratory: RV0484814) and FDA (FEI #: 3012063246). Valisure has also maintained voluntary registration status with the FDA.

243. Valisure states that "its mission is to help ensure the safety, quality and consistency of medications and supplements in the market."

244. On or about March 2, 2020, Valisure submitted a Citizen Petition ("the CP") to the FDA regarding its findings of high levels of contamination of various generic metformin products with an IARC- and EPA-listed probable human carcinogen known as NDMA.

245. Valisure's CP states that "the presence of NDMA in metformin products may be

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[55] *See* Quartz, A COMMON BLOOD-PRESSURE MEDICINE IS BEING RECALLED BECAUSE OF A TOXIC INGREDIENT, https://qz.com/1330936/the-fda-is-recalling-a-common-blood-pressure-drug-because-it-was-mixed-with-ndma/ (last accessed July 6, 2020).

[56] https://www.pharmaceuticalonline.com/doc/nitroso-impurities-in-valsartan-how-did-we-miss-them-0001.

[57] http://www.pharma.gally.ch/UserFiles/File/proofs%20of%20article.pdf.

primarily due to contamination during manufacturing as opposed to a fundamental instability of the drug molecule[.]"

246. Specifically with regard to generic Metformin products manufactured by Actavis, Valisure's testing (which closely followed the FDA own analytical methods) revealed NDMA contamination levels of between 180 and 345 ng/tablet, with levels reaching up to 7.6x the FDA's interim daily limit in Actavis's Metformin ER products.

Company	Dose (mg)	Type	Lot	NDMA (ng/tablet)	Common Tablets/Day	Times Over Acceptable Daily Intake Limit of NDMA
ACI Healthcare USA, Inc.	500	Metformin IR	D105061	31 +/- 4	4	1.3X
Actavis Pharma, Inc.	500	Metformin ER	1376339M	182 +/- 2	4	7.6X
Actavis Pharma, Inc.	750	Metformin ER	1354471A	320 +/- 25	2	6.7X
Amneal Pharmaceuticals LLC	750	Metformin ER	AM180770A	450 +/- 100	4	9.4X
Amneal Pharmaceuticals LLC	500	Metformin ER	AM180770 A	395 +/- 53 (623 +/- 28)*[58]	4	16.5X
Amneal Pharmaceuticals of New York LLC	500	Metformin ER	HD03319A	283 +/- 27	4	11.8X
Amneal Pharmaceuticals of New York LLC	500	Metformin ER	HD02918A	282 +/- 67	4	11.8X
Amneal Pharmaceuticals of New York LLC	850	Metformin IR	AM180405 A	235 +/- 17	2	4.9X
Apotex Corp.	500	Metformin ER	NE5801	90 +/- 3	4	3.8X
Ascend Laboratories, LLC	1000	Metformin IR	4200061B	529 +/- 107	2	11.0X
Aurobindo Pharma Limited	500	Metformin IR	MTSA190 16-B	30 +/- 7	4	1.3X
Granules Pharmaceuticals Inc.	500	Metformin ER	4910134A	41 +/- 5	4	1.7X

[58] The asterisk (*) denotes data generated by Emery Pharma from the same batch.

Company	Dose (mg)	Type	Lot	NDMA (ng/tablet)	Common Tablets/Day	Times Over Acceptable Daily Intake Limit of NDMA
Heritage Pharmaceuticals Inc.	850	Metformin IR	4510157A	254 +/- 12	2	5.3X
Heritage Pharmaceuticals Inc.	500	Metformin IR	4500753A	206 +/- 20	4	8.6X
Lupin Pharmaceuticals, Inc.	500	Metformin ER	G901203	122 +/- 11	4	5.1X
Time Cap Laboratories, Inc.	500	Metformin ER	XP9004	53 +/0 12	4	2.2X

247. Although the FDA has consistently stated that no levels of NDMA should be present in prescription drugs, it has set an interim safety limit of 96 ng/day purely out of drug shortage fears if all such products were recalled. Yet the MCDs manufactured by Defendants and other manufacturers of MCDs were found to be at least 1.3 times than the FDA limit, and as high as almost seventeen times the daily acceptable limit.

VII. Defendants Had Actual and/or Constructive Notice of NDMA Contamination of their Adulterated, Misbranded, and/or Unapproved MCDs

248. The FDA has concluded that "NDMA [is a] probable human carcinogen[ ] and should not be present in drug products." As alleged above, the MCDs manufactured by the API and Finished Dose Manufacturer defendants were found to contain dangerously high levels of nitrosamines, including NDMA, sometimes reaching levels many times higher than the FDA's interim safety limits.

249. NDMA is not an FDA-approved ingredient for Glucophage or Glucophage XR, or their generic equivalents. Moreover, none of Defendants' MCDs identify NDMA or other nitrosamines as an ingredient on the products' labels or elsewhere. This is because these

nitrosamines are probable human carcinogen active ingredients and are not approved to be included in metformin API. Their inclusion in Defendants' MCDs renders the MCDs adulterated and misbranded compared to Defendants' warranties and representations.

250. If Defendants had not routinely disregarded the FDA's cGMPs, including those discussed throughout this Complaint and the FDA's investigation reports and warning letters, and deliberately manipulated and ignored sampling data suggestive of impurities, or had fulfilled their quality assurance obligations, Defendants would have identified the presence of these nitrosamine contaminants almost immediately.

251. 21 C.F.R. § 211.110 contains the cGMPs regarding the "Sampling and testing of in-process materials and drug products[.]" Subsection (c) states the following:

> In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit, during the production process, e.g., at commencement or completion of significant phases or after storage for long periods.

21 C.F.R. § 211.110(c).

252. And as shown above, Defendants' quality control units are and were responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by each API manufacturer.

253. Also, as shown above, the quality control units for all of the manufacturing defendants were grossly deficient in fulfilling their responsibilities.

254. If these sampling-related and quality-control-related cGMPs were properly observed by Defendants, the nitrosamine contamination in Defendants' MCDs would have been discovered almost immediately, and Defendants were thus on (at minimum) constructive notice from the moment their MCDs became contaminated.

255. However, there are indications that Defendants had actual knowledge of their

MCDs' contamination with NDMA and tried to conceal or destroy the evidence.

256. And yet, Defendants knowingly, recklessly, and/or negligently introduced adulterated and/or misbranded MCDs containing dangerous amounts of nitrosamines into the U.S. market. Defendants failed to recall their generic MCDs because they feared permanently ceding market share to competitors. And Defendants issued the "voluntary" recall of their MCDs only after the FDA had threatened an involuntary recall.

D. Other Contaminants

257. Testing and evaluation are ongoing of MCDs manufactured, distributed, or sold by Defendants. Besides NDMA and NDEA, ongoing investigation suggests other impurities, such as NMBA, may exist as well in the MCDs at issue.

E. FDA Announces Voluntary Recall of Defendants' Adulterated and/or Misbranded MCDs

258. On or about December 5, 2019, the FDA announced that NDMA had been found in certain MCDs.

259. On June 11, 2020, the FDA published the names of the MCDs manufacturers who had initiated voluntary recalls, although the Valisure Citizen Petition had already named most or all such entities.

260. The recalls were initiated by Apotex Corp., Defendant Amneal, Time Cap Laboratories, Inc., Lupin Pharmaceuticals, Inc., and Defendants Teva and Actavis.

261. The recall of Defendants' MCDs is likely only the tip of the iceberg. Because of Defendants' and non-parties' ongoing fraud and deception, the full scope of Defendants' and non-parties' unlawful conduct is not yet known.

262. The recalled MCDs are worthless and were illegally distributed and sold to consumers and reimbursed by TPPs, causing economic loss to consumers and TPPs.

263. The recalls caused direct economic loss to consumers and TPPs. When the FDA announced the recalls of MCDs, consumers were notified (typically by their pharmacies among others) and were advised to obtain prescriptions for safe alternative drug to MCDs. Upon receipt of a prescription for a safe alternative drug, patients presented their prescriptions to be filled at a pharmacy and they and their TPPs paid for replacement drugs. Upon receipt of substitute drugs, patients stopped using Defendants' inferior recalled MCDs, which were worthless and illegally sold to them. Consumers and TPPs thereby paid to replace the recalled MCDs with substitute drugs, effectively paying twice for drugs intended to treat the same medical conditions and for use over the same (or an overlapping) time period, when they should only have paid once.

VIII. Defendants' Warranties and Fraudulent and Deceptive Statements to Consumers Regarding Their Generic MCDs

264. Each Defendant made and breached express and implied warranties and also made affirmative misrepresentations and omissions to consumers about their adulterated and/or misbranded MCDs.

A. Warranties Common to All Manufacturer Defendants

265. The FDA maintains a list of "Approved Drug Products with Therapeutic Equivalence Evaluations" known as the Orange Book.[59] The Orange Book is a public document; Defendants sought and received the inclusion of their MCDs products in the Orange Book upon approval of their ANDAs. In securing FDA approval to market generic MCDs in the United States as an Orange Book-listed drug, Defendants needed to demonstrate that their generic MCDs was bioequivalent to their RLDs.

[59] FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (ORANGE BOOK) SHORT DESCRIPTION, *at* https://www.fda.gov/drugs/informationondrugs/approveddrugs/approveddrugproductswiththerapeuticequivalenceevaluationsorangebook/default.htm (last accessed July 6, 2020).

266. Therapeutic equivalence for generic substitution is a continuing obligation on the part of the manufacturer. For example, according to the FDA's Orange Book, therapeutic equivalence depends in part on the manufacturer's continued compliance with cGMPs.

267. Each Defendant's MCD(s) is/are accompanied by an FDA-approved label. By presenting consumers with an FDA-approved MCD label, Defendants, as generic manufacturers, made representations and express or implied warranties to consumers and TPPs of the "sameness" of their products to the MCDs RLD, and that their products were consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels and/or were not adulterated and/or misbranded or misbranded.

268. By introducing their respective MCDs into the United States market as a therapeutic equivalent to their RLDs and with the FDA-approved label that is the same as that of the RLDs, Defendants represent and warrant to end-users and TPPs that their MCDs are in fact the same as and are therapeutically interchangeable with their RLDs. Much of the generic drugs supply chain, including the most critical components of that supply chain (end-user patients and reimbursing TPPs) rely on these representations and warranties.

269. In addition, each Defendant affirmatively misrepresented and warranted to consumers and TPPs through their websites, brochures, and other marketing or informational materials that their MCDs complied with cGMPs and did not contain (or were not likely to contain) any ingredients besides those identified on the products' FDA-approved labels.

270. The presence of nitrosamines in Defendants' MCDs: (1) renders Defendants' MCDs non-bioequivalent (i.e., not the same) to their RLDs and thus non-therapeutically interchangeable with them, thus breaching Defendants' express warranties of sameness; (2) was the result of gross deviations from cGMPs rendering Defendants' MCDs non-therapeutically equivalent to their

RLDs, thus breaching Defendants' express warranties of sameness; and (3) results in Defendants' MCDs containing an ingredient that is not also contained in their RLDs, also breaching Defendants' express warranty of sameness (and express warranty that the products contained the ingredients listed on each Defendant's FDA-approved label). Each Defendant willfully, recklessly, or negligently failed to ensure their MCDs' labels and other advertising or marketing statements accurately conveyed information about their products.

271. The presence of nitrosamines in Defendants' MCDs and Defendants' serial and willful failures to comply with cGMPs and other shortcomings in Defendants' generic drug manufacturing processes have resulted in Defendants' MCDs being adulterated and/or misbranded compared to Defendants' representations and warranties.

272. At all relevant times, Defendants have also impliedly warranted that their MCDs were merchantable and fit for their ordinary purposes.

273. Naturally, due to their status as probable human carcinogens as listed by both the IARC and the U.S. EPA, nitrosamines including NDMA are not FDA-approved ingredients in MCDs. The presence of NDMA and other similar nitrosamines or impurities in Defendants' MCDs means that Defendants have violated implied warranties to Plaintiffs and Class Members. The presence of NDMA in Defendants' MCDs makes Defendants' MCDs non-merchantable and not fit for its ordinary purposes (i.e., as a therapeutically interchangeable generic version of their RLDs), breaching Defendants' implied warranty of merchantability and/or fitness for ordinary purposes.

274. For these and other reasons, Defendants' MCDs are therefore adulterated, misbranded, and/or unapproved, and it was illegal for Defendants' to have introduced such MCDs in the United States. See 21 U.S.C. §§ 331(a), 351(a)(2)(B), 331(g).

275. Adulterated, misbranded, and/or unapproved MCDs contaminated with cancer-

causing compounds are essentially worthless. No reasonable consumer (including Plaintiffs) would purchase (or reimburse for) these nitrosamine laden MCDs. Nor could they, as an adulterated, misbranded, and/or unapproved MCDs cannot even be legally sold or purchased within the United States. At a minimum, adulterated, misbranded, and/or unapproved MCDs were worth less than their non-contaminated equivalents. Further, adulterated, misbranded, and/or unapproved MCDs do not possess the same safety and efficacy profile as their branded equivalents. As such, the MCDs were not what they were supposed to be.

276. Moreover, every consumer (and every TPP's insured) who purchased and ingested MCDs, including Plaintiffs (or Plaintiffs' insureds), has been exposed to a non-bargained for carcinogenic agent with mutagenic properties that operates at the cellular and sub-cellular levels, and may give rise to future potential health consequences.

277. The recalls were meant to quickly remove unsafe products from the market. While the FDA advised patients to continue taking MCDs, it only did so because of the risks associated with untreated high blood pressure.

278. In response to the recall, pharmacies and health care providers throughout the United States contacted affected patients to advise them of the recall and to recommend that they contact their doctors to request a replacement or an alternative treatment option.

279. Because of the seriousness of the impurity—unsafe levels of a carcinogen— all or virtually all patients immediately stopped taking the tainted drug products after receiving notice of the recall. They were prescribed a safe alternative. MCDs had no use and were discarded.

B. Actavis/Teva's Warranties

280. Teva has a "Generics FAQs" on its website.[60] In response to the question "Are generic drugs safe?" Teva states the following:

> A generic drug is bioequivalent to the original innovative drug and meets the same quality standards. The active ingredient, the content, the dosage form and the usage of a generic drug are similar to those of an innovative drug. Generic drugs are essentially the same as the original drug, but are offered at a lower price.

281. In response to the question "How do you ensure generic drug safety, having tried it in only a limited number of patients?" Teva states the following:

> The generic product's active pharmaceutical ingredient (API) is identical to that of the innovative drug, its purity profile is similar, and it is found to be bioequivalent; therefore its safety and efficacy are also comparable.

282. Similarly, under the webpage titled "Uncompromising Quality," Teva states that it knows that its products affect patient health. Teva further states that it "guarantee[s] the quality of our products" with through Teva's "impeccable adherence to … [cGMPs][.]"

283. Teva's website states that "Our state-of-the-art manufacturing facilities feature the most advanced testing equipment to guarantee the quality of our products. Equipment is tested and certified, and every manufacturing process is validated. All supplier procedures are strictly supervised to ensure that only the highest-grade materials are used in our products."[61]

284. According to Teva, "[o]ur manufacturing network is continuously optimized so that our customers can have full confidence in our supply chain. This is enabled by high-volume, technologically-advanced distribution facilities. These facilities allow us to deliver new products

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[60] Teva, PRODUCTS, *at* http://www.tevapharm.com/our_products/generic_qa/ (last accessed July 6, 2020).

[61] Teva, Company PROFILE: UNCOMPROMISING QUALITY, https://www.tevapharm.com/about/profile/quality_assurance/ (last accessed July 6, 2020).

swiftly and reliably. We continually review our capabilities and capacity. This ensures that we can consistently deliver best-in-class products. Our customers know that their end-consumers are receiving high-quality healthcare and wellness pharmaceuticals."[62]

285. In a May 16, 2018 catalog of "all Teva and Actavis products," Teva, Actavis, Teva USA, Arrow, and Actavis Pharma all stated that their MCDs were "bioequivalent" to their RLDs.

286. Teva USA's website states, "Teva's commitment to quality is uncompromising and we manufacture according to the highest quality and compliance standards. This focus is evident at every stage of the development and production of our medicines. All of our manufacturing processes are validated and products are tested and certified, using state-of-the-art testing equipment throughout the manufacturing process designed to ensure adherence to the highest quality and compliance standards."[63]

287. Teva USA's Code of Conduct affirms, "To ensure we are in compliance and working in accordance with sound quality principles in our research laboratories, in our clinical trials, and in our manufacturing plants and distribution centers, we adhere to the systems and internal controls for 'Good Operating Practices,' or 'GxP,' including Good Laboratory Practices (GLP), Good Clinical Practices (GCP), Good Manufacturing Practices (GMP) Good Pharmacovigilance Practices (GVP) and Good Distribution Practices (GDP)."[64]

288. Teva USA maintains a Brand-to-Generic Medication Reference on its website.[65] This Reference includes MCDs and their RLD equivalents, including specifically Metformin

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[62] *Id.*
[63] Teva USA, ABOUT TEVA: QUALITY YOU CAN TRUST, https://www.tevausa.com/About-Teva/article-pages/quality/ (last accessed July 6, 2020).
[64] Teva USA, TEVA CODE OF CONDUCT, https://www.tevausa.com/About-Teva/article-pages/Code-of-Conduct/ (last accessed July 6, 2020).
[65] Teva USA. PATIENTS: RESOURCES, https://www.tevagenerics.com/patients/resources/ (last accessed July, 2020).

Hydrochloride ER tablets, and the brand equivalent Glumetza.

C. The Emcure/Avet/Granules Warranties

289. The first sentence one reads after landing on Avet's website is as follows:

> Avet provides high quality generic medicines that help patients and practitioners achieve affordable healthcare solutions. Our global supply chain network is built around centers of manufacturing and scientific excellence to provide you with the highest level of quality, safety, value and service in generics.[66]

290. On its website under the "Generics Overview" section, Avet asserts that its "[g]eneric drugs contain the same active ingredients, in the very same strength, as brand-name drugs."[67]

291. Avet continues by stating that "[g]eneric drugs are well accepted for substitution of brand-name drugs as they sell at a discount to the branded product's price and have been determined to be their equivalent in quality and efficacy. They must meet the same governmental and FDA quality and effectiveness standards as the brand."

292. After this statement, Avet lists its Metformin Hydrochloride Tablets, USP, and references the brand version RLD Glucophage.

293. Part of Avet's FDA approved labeling is a so-called patient information leaflet that is distributed with each prescription. The Avet leaflet includes the following question and answer:

What are the ingredients of metformin hydrochloride tablets?

Active ingredients of Metformin hydrochloride tablets: metformin hydrochloride.

Inactive ingredients in each tablet of metformin hydrochloride tablets: Povidone (k-30), Povidone (k-90), pregelatinized starch, and magnesium stearate. In addition, the coating for the tablet contains artificial blackberry flavor, hypromellose, macrogol and titanium dioxide.

[66] http://avetpharma.com (last visited June 26, 2020).
[67] http://avetpharma.com/products/ (last visited June 26, 2020).

294. Defendant Avet warrants that the above-listed items are the active and inactive ingredients, and fails to disclose that NDMA is an active ingredient in Avet's MCDs.

295. Avet also has a "Patients"[68] section of its website that includes the following warranties and representations about Avet's quality generic medications:

Frequently Asked Questions about Generics

Are generic drugs as good as brand-name?
Generic pharmaceutical manufacturers must prove to the FDA that their version of a drug:

- contains the same active ingredient;
- is identical in strength, dosage form, and route of administration;
- has the same indications, dosing, and labeling; and
- provides the same efficacy and safety profile to patients ("bioequivalent")

Are generic drugs safe?
Generic medicines have to be safe and effective to be approved by the FDA. The FDA also requires generic manufacturers to:

- meet the same batch-to-batch requirements for strength, purity, and quality as the original manufacturer; and
- follow the same strict "Good Manufacturing Practices" rules.

296. Avet expressly warrants to patients that its MCDs are "as good as" the RLDs, and "safe" because Avet "follows … strict "Good Manufacturing Practices" rules." But Avet was not and is not following federal cGMPs and is breaching express and implied warranties in this regard.

297. Emcure, which is Avet's parent company, states that one of its "core values" is "quality & patient focus" while another is "integrity."[69]

298. Emcure also touts its "world-class manufacturing infrastructure with several facilities located across India & USA."[70]

299. Defendant Granules (which entered into a strategic alliance with Avet for metformin), lists metformin as one of its "core molecules" forming its "core business" and states that it holds a "leadership position" with regard to metformin.[71] Granules touts its scaling

[68] http://avetpharma.com/faqs/ (last visited June 26, 2020).
[69] https://www.emcure.com/aboutus (last visited June 27, 2020).
[70] https://www.emcure.com (last visited June 27, 2020).
[71] http://www.granulesindia.com/about-us.php (last visited June 27, 2020).

efficiencies, stating that it has "inherent strength in efficient manufacturing of high-volume pharmaceutical products" such as metformin.

300. Granules states on its website that its core values include "integrity" "quality" and being "customer centric," which Granules defines as "focus[ing] our energies toward understanding and addressing customer expectations[.]"[72]

301. Granules lists Metformin HCl as one of its API formulations for which it has USFDA approval and a DMF on file,[73] and lists Metformin IR and Metformin XR as among finished dosages it manufactures.[74]

302. Granules is also leaning heavily into the U.S. market, announcing that it "recently bought a facility in Chantilly, Virginia."

D. Amneal Defendants' Warranties

303. Amneal asserts that it has a "reputation for quality" and has an entire section of its website under the name "Our Purpose & Commitments."

304. Amneal states it "produce[s] quality generic, specialty and biosimilar medicines."[75] Amneal proudly proclaims that its "quality culture is one of the core pillars of our success." [76]

305. Amneal also touts its success in "consistently meet[ing] or exceed[ing] quality, industry and global regulatory standards."[77]

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[72] http://www.granulesindia.com/about-us-vision-mission-values.php#vision-mission-values (last visited June 27, 2020).
[73] http://www.granulesindia.com/pdf/API.pdf (last visited June 27, 2020).
[74] http://www.granulesindia.com/pdf/Dosage.pdf (last visited June 27, 2020).
[75] Amneal, Products: Our Portfolio, https://www.amneal.com/products/our-portfolio/ (last accessed June 17, 2020).
[76] Amneal, Products: Quality, https://www.amneal.com/products/quality/ (last accessed June 17, 2020).
[77] Amneal, Products: Quality, https://www.amneal.com/products/quality/ (last accessed June 17, 2020).

306. As part of their corporate "Purpose and Commitment," Amneal sets "a high bar for our products, pipeline, operations and service—always going the extra mile to exceed expectations and reliably execute in everything we do… because patients' lives depend on it." [78]

307. Amneal's SEC filings acknowledge manufacturers are "required to comply with cGMP standards at all times during the production and processing of pharmaceuticals, and the FDA may inspect the manufacturer's sites at any time to ensure compliance."[79] Amneal further recognizes "its products must be made in a manner consistent with cGMP" in the United States and around the globe and maintains it is "committed to continuing to improve [its] quality control and manufacturing practices."

E. Aurobindo Defendants' Warranties

308. Aurobindo's website states that it is "Committed to Quality and Safety."[80]

309. According to Aurobindo USA, "[a]s a truly integrated company, we assure continuity and quality from start to finish."[81] Aurobindo also "[s]eek[s] to attain the highest quality standards."[82]

310. Aurolife states, "The Aurolife family consists of an experienced management team with expertise in manufacturing, R&D, Quality Assurance and Quality control, finance and regulatory affairs. Aurolife has 100,000 square feet state-of-the-art US FDA approved cGMP

[78] Amneal, About: Our Purpose, https://www.amneal.com/about/our-purpose-commitments/ (last accessed June 17, 2020).
[79] http://www.annualreports.com/HostedData/AnnualReports/PDF/NYSE_AMRX_2019.pdf
[80] Aurobindo, HOMEPAGE, https://www.aurobindo.com/ (last visited July 6, 2020).
[81] Aurobindo USA, AUROCONTROL, https://www.aurobindousa.com/company/our-story/aurocontrol/ (last accessed July 6, 2020).
[82] Aurobindo USA, OUR STORY, https://www.aurobindousa.com/company/our-story/ (last accessed July 6, 2020).

compliant manufacturing facility with an investment of over US $50 million."[83]

F. Alkem/Ascend Defendants' Warranties

311. Alkem loftily describes its work as having the potential to "create marvels that can influence generations." [84]

312. Alkem describes an "obsession" with maintaining a "culture of high quality" through all of its operations.[85]

313. As part of this "culture of high quality," Alkem touts its "state-of-the-art facilities that employ cutting-edge manufacturing techniques for producing best-in-class products." To this end, Alkem claims to have a management that "furnishes adequate resources to ensure quality deliverance" equipping every facility with "Quality Control Units that assure quality at each stage." [86]

314. Alkem even goes on so far as to include demonstrative evidence of their commitment to quality, allowing consumers and TPPs to "tour"[87] its "world class facilities, and see laboratory employees at work:

[83] Aurolife, ABOUT AUROLIFE, http://aurolifepharma.com/aboutus.html (last accessed June 5, 2019).
[84] https://www.alkemlabs.com/about-us.php (last accessed June 30, 2020).
[85] https://www.alkemlabs.com/manufacturing-facilities.php (last accessed June 30, 2020).
[86] *Id.*
[87] https://www.alkemlabs.com/facility-tour.php (last accessed July 6, 2020).

315. Alkem's United States Operations, Ascend, describes itself as one of the "fastest growing companies in terms of generic drug sales." [88]

316. Ascend states that its "commitment to research" resulted in the filing of over 125 ANDAs with the FDA, which has resulted in Ascend's products being made available at "major pharmacy chains, distributors, and pharmaceutical retailers." [89]

G. Warranties Common to All Retail Pharmacy Defendants

317. Retail pharmacies are where consumers purchase and fill prescriptions for pharmaceuticals. As a result, retail pharmacies and consumers have direct privity of contract. With each sale of prescription drugs, retail pharmacies impliedly warrant to consumers that the prescription drugs being sold to them are merchantable and/or fit for its ordinary uses.

318. By selling pharmaceutical prescription drugs in the stream of commerce, each retail pharmacy defendant warrants that the generic drugs for which they receive payments from are the same as existing brand-named drugs in active ingredient, dosage form, safety, strength, methods of administration, quality, and performance characteristics. More generally, retail pharmacy

[88] https://www.alkemlabs.com/us.php
[89] *Id.*

defendants warrant that prescription drugs they sell are of a standard quality.

319. On account of the existence of these strict liability implied warranties, most retail pharmacies secure indemnification from manufacturer defendants for breach of such warranties.

320. Further, each retail pharmacy defendant is obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including adulterated and/or misbranded) drugs.

H. Wholesale Distributor Defendants' Warranties

321. Each distributor defendant is obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including adulterated and/or misbranded) drugs.

IX. Fraudulent Concealment and Tolling

322. Plaintiffs' and Class Members' causes of action accrued on the date the FDA announced the recall of Defendants' generic MCDs.

323. Alternatively, any statute of limitation or prescriptive period is equitably tolled on because of fraudulent concealment. Defendants each affirmatively concealed from Plaintiffs and other Class Members their unlawful conduct. Each Defendant affirmatively strove to avoid disclosing their knowledge of their and other Defendants' cGMP violations with related to their MCDs, and of the fact that their MCDs were adulterated and/or misbranded and contaminated with nitrosamines, and were not the same as their RLDs.

324. For instance, no Defendant revealed to the public that their MCDs contained nitrosamines or was otherwise adulterated, misbranded, and/or unapproved, or non-therapeutically equivalent to their RLDs until the FDA's recall announcement in June 2020. The FDA information that preceded the recall announcement is heavily redacted (including the names of the drugs

affected by Defendants' respective cGMP violations accounted above), and prior inspection reports or warnings were not fully available to the public, if at all.

325. To the contrary, each Defendant continued to represent and warrant that their generic MCDs were the same as and therapeutically interchangeable with their RLDs.

326. Because of this, Plaintiffs and other Class Members did not discover, nor could they have discovered through reasonable and ordinarily diligence, each Defendant's deceptive, fraudulent, and unlawful conduct alleged herein. Defendants' false and misleading explanations, or obfuscations, lulled Plaintiffs and Class Members into believing that the prices paid for their MCDs were appropriate for what they believed to be non-adulterated or misbranded drugs despite their exercise of reasonable and ordinary diligence.

327. As a result of each Defendant's affirmative and other acts of concealment, any applicable statute of limitations affecting the rights of Plaintiffs and other Class Members has been tolled. Plaintiffs and/or other Class Members exercised reasonable diligence by among other things promptly investigating and bringing the allegations contained herein. Despite these or other efforts, Plaintiffs were unable to discover, and could not have discovered, the unlawful conduct alleged herein at the time it occurred or at an earlier time so as to enable this complaint to be filed sooner.

A. New Revelations Continue to Unfold About Other Manufacturing Plants

328. The recall of Defendants' MCDs is likely only the tip of the iceberg. Because of Defendants' and non-parties' ongoing fraud and deception, the full scope of Defendants' and non-parties' unlawful conduct is not yet known.

X. CLASS ACTION ALLEGATIONS

329. Plaintiffs seek to represent a Nationwide Class pursuant to Fed. R. Civ. P. 23(a), 23(b)(2) and 23(b)(3) as defined below:

> All individuals and entities in the United States and its territories and possessions who paid any amount of money for a metformin-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by any Defendant.

330. The Nationwide Class has two sub-classes:

> All consumers in the United States and its territories and possessions who paid any amount of money for a metformin-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by any Defendant.
>
> All TPPs in the United States and its territories and possessions that paid any amount of money for a metformin-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by any Active Pharmaceutical Ingredient, Finished Dose, Wholesaler Defendant.

331. Plaintiffs allege additional sub-classes for all individuals and TPPs in each State, territory, or possession – or combination(s) of States, territories, or possessions to the extent class members from these jurisdictions can be grouped together for purposes of class treatment – who, paid any amount of money out of pocket for a metformin-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by any Defendant (collectively, the Subclasses"). These include but are not limited to the following:

a. Plaintiffs Brzozowski and Harris seek to represent a New Jersey sub-class and/or subclass(es) of states with similar applicable laws to New York.

b. Plaintiffs Mantalis seeks to represent a New York sub-class and/or subclass(es) of states with similar applicable laws to New York.

c. Plaintiffs Wineinger seeks to represent an Indiana sub-class and/or subclass(es) of states with similar applicable laws to Indiana.

d. Plaintiffs Hann, Rahman, and Wohlmuth seek to represent a California sub-class and/or sub-classes of states with similar applicable laws to California.

332. Collectively, the foregoing Nationwide Class and the Sub-classes are referred to as the "Class."

333. Excluded from the Class are: (a) any judge or magistrate presiding over this action, and members of their families; (b) Defendants and affiliated entities, and their employees, officers, directors, and agents; (c) Defendants' legal representatives, assigns and successors; and (d) all persons who properly execute and file a timely request for exclusion from any Court-approved class.

334. Plaintiffs reserve the right to narrow or expand the foregoing class definition, or to create or modify subclasses as the Court deems necessary.

335. Plaintiffs meet the prerequisites of Rule 23(a) to bring this action on behalf of the Class.

336. **Numerosity**: While the exact number of Class Members cannot be determined without discovery, they are believed to consist of potentially millions of metformin consumers nationwide. The Class Members are therefore so numerous that joinder of all members is impracticable.

337. **Existence and predominance of common questions of law and fact:** Common questions of law and fact exist as to all Class and Sub-Class and predominate over any questions affecting on individual Class and Sub-class members. These common legal and factual questions include, but are not limited to, the following:

a. Whether each Defendant made express or implied warranties of "sameness" to Plaintiffs and Class Members regarding their generic MCDs;

b. Whether each Defendant's MCDs were, in fact, the same as their RLDs consistent with such express or implied warranties;

c. Whether each Defendant's MCDs were contaminated with NDMA, NDEA, or similar contaminants;

d. Whether each Defendant's MCDs containing NMDA, NDEA, or similar contaminants were adulterated and/or misbranded;

e. Whether Defendants violated cGMPs regarding the manufacture of their MCDs;

f. Whether each Defendant falsely claimed that its MCDs were the same as their RLDs and thus therapeutically interchangeable;

g. Whether each Defendant affirmatively misrepresented or omitted facts regarding its compliance with cGMPs;

h. Whether Plaintiffs and other Class Members have been injured as a result of each Defendant's unlawful conduct, and the amount of their damages;

i. Whether a common damages model can calculate damages on a class-wide basis;

j. When Plaintiffs' and Class Members' causes of action accrued; and

k. Whether Defendants fraudulently concealed Plaintiffs' and Class Members' causes of action.

338. Typicality: Plaintiffs' claims are typical of Class Members' claims. Plaintiffs and Class Members all suffered the same type of economic harm. Plaintiffs have substantially the same interest in this matter as all other Class Members, and their claims arise out of the same set of facts and conduct as the claims of all other Class Members.

339. Adequacy of Representation: Plaintiffs are committed to pursuing this action and have retained competent counsel experienced in pharmaceutical litigation, consumer fraud litigation, class actions, and federal court litigation. Accordingly, Plaintiffs and their counsel will fairly and adequately protect the interests of Class Members. Plaintiffs' claims are coincident with,

and not antagonistic to, those of the other Class Members they seek to represent. Plaintiffs have no disabling conflicts with Class Members and will fairly and adequately represent the interests of Class Members.

340. The elements of Rule 23(b)(2) are met. Defendants have acted on grounds that apply generally to Class Members so that preliminary and/or final injunctive relief and corresponding declaratory relief is appropriate respecting the Class as a whole.

341. Superiority: A class action is superior to all other available means for the fair and efficient adjudication of this controversy. Although many other Class Members have claims against Defendants, the likelihood that individual Class Members will prosecute separate actions is remote due to the time and expense necessary to conduct such litigation. Serial adjudication in numerous venues would not be efficient, timely or proper. Judicial resources would be unnecessarily depleted by resolution of individual claims. Joinder on an individual basis of thousands of claimants in one suit would be impractical or impossible. In addition, individualized rulings and judgments could result in inconsistent relief for similarly situated Plaintiffs. Plaintiffs' counsel, highly experienced in pharmaceutical litigation, consumer fraud litigation, class actions, and federal court litigation, foresee little difficulty in the management of this case as a class action.

FIRST COUNT
BREACH OF EXPRESS WARRANTIES
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

342. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

343. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

344. Plaintiffs, and each member of the Class, formed a contract with Defendants at the

time Plaintiffs and the other Class members purchased the MCDs. The terms of the contract include the promises and affirmations of fact made by Defendants on the MCDs' packaging and through marketing and advertising, including that the product would be bioequivalent to the name-brand medication, and would be of same "quality" and have the same safety and efficacy profile as the RLD. This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract between Plaintiffs and the members of the Class and Defendants.

345. Each Defendant expressly warranted that its MCDs were fit for its ordinary use as an FDA-approved generic pharmaceutical that is therapeutically equivalent to and interchangeable with their RLDs. In other words, Defendants expressly warranted that their products were the same as their RLDs.

346. Each Defendant sold MCDs that they expressly warranted were compliant with cGMP and not adulterated or misbranded.

347. Each Defendant's MCDs did not conform to each Defendant's express representations and warranties because the product was not manufactured in compliance with cGMP and was adulterated and misbranded.

348. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-313; Alaska Stat. § 45.02.313; Ariz. Rev. Stat. Ann. § 47-2313; Ark. Code. Ann. § 4-2-313; Cal. Com. Code § 2313; Colo. Rev. Stat. § 4-2-313; Conn. Gen. Stat. Ann. § 42a-2-313; 6 Del. Code. § 2-313; D.C. Code. § 28:2-313; Fla. Stat. Ann. § 672.313; Ga. Code. Ann. § 11-2-313; Haw. Rev. Stat. § 490:2-313; Idaho Code § 28-2-313; 810 Ill. Comp. Stat. Ann. 5/2-313; Ind. Code Ann. § 26-1-2-313; Kan.

Stat. Ann. § 84-2-313; Ky. Rev. Stat. Ann. § 355.2-313; 11 Me. Rev. Stat. Ann. § 2-313; Md. Code. Ann. § 2-313; Mass. Gen. Law Ch. 106 § 2-313; Mich. Comp. Laws Ann. § 440.2313; Minn. Stat. Ann. § 336.2-313; Miss. Code Ann. § 75-2-313; Mo. Rev. Stat. § 400.2-313; Mont. Code Ann. § 30-2-313; Nev. Rev. Stat. U.C.C. § 104.2313; N.H. Rev. Ann. § 382-A:2-313; N.J. Stat. Ann. § 12A:2-313; N.M. Stat. Ann. § 55-2-313; N.Y. U.C.C. Law § 2-313; N.C. Gen. Stat. Ann. § 25-2-313; N.D. Stat. § 41-02-313; Ohio Rev. Code Ann. § 1302.26; Okla. Stat. tit. 12A § 2-313; Or. Rev. Stat. § 72.3130; 13 Pa. C.S. § 2313; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-313; S.C. Code Ann. § 36-2-313; S.D. Stat. § 57A-2-313; Tenn. Code Ann. § 47-2-313; Tex. Bus. & Com. Code Ann. § 2-313; Utah Code Ann. § 70A-2-313; Va. Code § 8.2-313; Vt. Stat. Ann. 9A § 2-313; W. Va. Code § 46-2-313; Wash. Rev. Code § 62A 2-313; Wis. Stat. Ann. § 402.313 and Wyo. Stat. § 34.1-2-313.

349. At the time that each Defendant marketed and sold its MCDs, they recognized the purposes for which the products would be used, and expressly warranted the products were the same as their RLDs, and cGMP compliant and not adulterated or misbranded. These affirmative representations became part of the basis of the bargain in every purchase by Plaintiffs and other Class Members including but not limited to express representations made in referring to their MCDs.

350. Each Defendant breached its express warranties with respect to its MCDs as they were not of merchantable quality, were not fit for their ordinary purpose, and did not comply with cGMP and was adulterated and misbranded.

351. Plaintiffs and each member of the Class would not have purchased the MCDs had they known these drugs were not the same as the RLD, did not contain the same ingredients, did not have the same safety and efficacy profile of the RLD, and contained NDMA and NDEA.

352. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages in the amount of the purchase price of their medications, the purchase price of any replacement medications, and any consequential damages resulting from the purchases, in that the MCDs they purchased were so inherently flawed, unfit, or unmerchantable as to have no market value.

SECOND COUNT
BREACH OF EXPRESS WARRANTIES
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

353. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

354. This cause of action is alleged on behalf of TPP Class Members against all Defendants except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

355. Each Defendant expressly warranted that its MCDs were fit for its ordinary use, i.e., as an FDA-approved generic pharmaceutical that is therapeutically to and interchangeable with their RLDs. In other words, Defendants expressly warranted that their products were the same as their RLDs.

356. Each Defendant sold MCDs that they expressly warranted were compliant with cGMP and/or not adulterated and/or misbranded.

357. Each Defendant's MCDs did not conform to each Defendant's express representations and warranties because the product was not manufactured in compliance with cGMP and was adulterated and misbranded.

358. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied

warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-313; Alaska Stat. § 45.02.313; Ariz. Rev. Stat. Ann. § 47-2313; Ark. Code. Ann. § 4-2-313; Cal. Com. Code § 2313; Colo. Rev. Stat. § 4-2-313; Conn. Gen. Stat. Ann. § 42a-2-313; 6 Del. Code. § 2-313; D.C. Code. § 28:2-313; Fla. Stat. Ann. § 672.313; Ga. Code. Ann. § 11-2-313; Haw. Rev. Stat. § 490:2-313; Idaho Code § 28-2-313; 810 Ill. Comp. Stat. Ann. 5/2-313; Ind. Code Ann. § 26-1-2-313; Kan. Stat. Ann. § 84-2-313; Ky. Rev. Stat. Ann. § 355.2-313; 11 Me. Rev. Stat. Ann. § 2-313; Md. Code. Ann. § 2-313; Mass. Gen. Law Ch. 106 § 2-313; Mich. Comp. Laws Ann. § 440.2313; Minn. Stat. Ann. § 336.2-313; Miss. Code Ann. § 75-2-313; Mo. Rev. Stat. § 400.2-313; Mont. Code Ann. § 30-2-313; Nev. Rev. Stat. U.C.C. § 104.2313; N.H. Rev. Ann. § 382-A:2-313; N.J. Stat. Ann. § 12A:2-313; N.M. Stat. Ann. § 55-2-313; N.Y. U.C.C. Law § 2-313; N.C. Gen. Stat. Ann. § 25-2-313; N.D. Stat. § 41-02-313; Ohio Rev. Code Ann. § 1302.26; Okla. Stat. tit. 12A § 2-313; Or. Rev. Stat. § 72.3130; 13 Pa. C.S. § 2313; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-313; S.C. Code Ann. § 36-2-313; S.D. Stat. § 57A-2-313; Tenn. Code Ann. § 47-2-313; Tex. Bus. & Com. Code Ann. § 2-313; Utah Code Ann. § 70A-2-313; Va. Code § 8.2-313; Vt. Stat. Ann. 9A § 2-313; W. Va. Code § 46-2-313; Wash. Rev. Code § 62A 2-313; Wis. Stat. Ann. § 402.313 and Wyo. Stat. § 34.1-2-313.

359. At the time that each Defendant marketed and sold its MCDs, they recognized the purposes for which the products would be used, and expressly warranted the products were the same as their RLDs, and cGMP compliant and not adulterated or misbranded. These affirmative representations became part of the basis of the bargain in every purchase by Plaintiffs and other Class Members, including but not limited to express representations made in referring to their MCDs.

360. Each Defendant breached its express warranties with respect to its MCDs as they

were not of merchantable quality, were not fit for its ordinary purpose, and did not comply with cGMP and were adulterated and misbranded.

361. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants' MCDs they purchased were so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value.

THIRD COUNT
BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY (INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

362. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

363. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

364. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2-314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; La. Civ. Code Ann. Art. § 2520; 11 Me. Rev. Stat. Ann. § 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2-314; Mo. Rev. Stat. § 400.2-314; Mont. Code Ann. § 30-2-314; Nev. Rev. Stat. U.C.C. § 104.2314; N.H. Rev. Ann. § 382-A:2-314; N.J.

Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-2-314; N.Y. U.C.C. Law § 2-314; N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314; Ohio Rev. Code Ann. § 1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa. C.S. § 2314; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-314; S.C. Code Ann. § 36-2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. § 47-2-314; Tex. Bus. & Com. Code Ann. § 2-314; Utah Code Ann. § 70A-2-314; Va. Code § 8.2-314; Vt. Stat. Ann. 9A § 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. § 402.314 and Wyo. Stat. § 34.1-2-314.

365. Each Defendant was a merchant within the meaning of the above statutes.

366. Each Defendant's MCDs constituted "goods" or the equivalent within the meaning of the above statutes.

367. Each Defendant was obligated to provide Plaintiffs and other Class Members reasonably fit MCDs for the purpose for which the product was sold, and to conform to the standards of the trade in which Defendants are involved such that the product was of fit and merchantable quality.

368. Each Defendant knew or should have known that its MCDs were being manufactured and sold for the intended purpose of human consumption as a therapeutic equivalent to their RLDs (or is strictly liable in the event of lack of actual or constructive knowledge), and impliedly warranted that their MCDs were of merchantable quality and fit for that purpose.

369. Each Defendant breached its implied warranty because each Defendant's MCDs were not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.

370. Plaintiffs and other Class members purchased the MCDs in reliance upon Defendants' skill and judgment and the implied warranties of fitness for the purpose.

371. The MCDs were not altered by Plaintiffs or Class members.

372. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants' MCDs they purchased was so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value.

FOURTH COUNT
BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY (INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

373. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

374. This cause of action is alleged on behalf of TPP Class Members against all Defendants except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

375. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2-314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; La. Civ. Code Ann. Art. § 2520; 11 Me. Rev. Stat. Ann. § 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2-314; Mo. Rev. Stat. § 400.2-314; Mont. Code Ann. § 30-2-314; Nev. Rev. Stat. U.C.C. § 104.2314; N.H. Rev. Ann. § 382-A:2-314; N.J.

Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-2-314; N.Y. U.C.C. Law § 2-314; N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314; Ohio Rev. Code Ann. § 1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa. C.S. § 2314; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-314; S.C. Code Ann. § 36-2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. § 47-2-314; Tex. Bus. & Com. Code Ann. § 2-314; Utah Code Ann. § 70A-2-314; Va. Code § 8.2-314; Vt. Stat. Ann. 9A § 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. § 402.314 and Wyo. Stat. § 34.1-2-314.

376. Each Defendant was a merchant within the meaning of the above statutes.

377. Each Defendant's MCDs constituted "goods" or the equivalent within the meaning of the above statutes.

378. Each Defendant was obligated to provide Plaintiffs and other Class Members reasonably fit MCDs for the purpose for which the product was sold, and to conform to the standards of the trade in which Defendants are involved such that the product was of fit and merchantable quality.

379. Each Defendant knew or should have known that its MCDs were being manufactured and sold for the intended purpose of human consumption as a therapeutic equivalent to their RLDs (or is strictly liable in the event of lack of actual or constructive knowledge), and impliedly warranted that same was of merchantable quality and fit for that purpose.

380. Each Defendant breached its implied warranty because each Defendant's MCDs were not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.

381. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants'

MCDs they purchased were so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value.

FIFTH COUNT
MAGNUSON-MOSS WARRANTY ACT, 15 U.S.C. § 2301, *ET SEQ.*
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

382. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

383. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

384. Each Defendant is a "warrantor" within the meaning of the Magnuson-Moss Warranty Act.

385. Plaintiffs and other Class Members are "consumers" within the meaning of the Magnuson-Moss Warranty Act.

386. Each Defendant expressly or impliedly warranted their MCDs as alleged in the First and Second Causes of Action.

387. Under 15 U.S.C. § 2310(d)(1), Plaintiffs and Other Class Members were "damaged by the failure of a supplier, warrantor, or service contractor to comply with any obligation under this chapter, or under a written warranty, implied warranty, or service contract, may bring suit for damages and other legal and equitable relief." 15 U.S.C. § 2310(d)(1). Plaintiffs sue pursuant to this section to recover money damages and for legal and equitable relief on behalf of itself and the Class Members.

388. No Defendant has acted on the opportunity to cure its failure with respected to its warranted MCDs.

389. Likewise, pursuant to 15 U.S.C. § 2310(d)(2), upon prevailing in this action,

Plaintiffs are entitled to receive an award of attorneys' fees and expenses and pray for the same.

SIXTH COUNT
MAGNUSON-MOSS WARRANTY ACT, 15 U.S.C. § 2301, *ET SEQ.*
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

390. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

391. This cause of action is alleged on behalf of TPP Class Members against all Defendants except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

392. Each Defendant is a "warrantor" within the meaning of the Magnuson-Moss Warranty Act.

393. Plaintiffs and other Class Members are "consumers" within the meaning of the Magnuson-Moss Warranty Act.

394. Each Defendant expressly or impliedly warranted their MCDs as alleged in the First and Second Causes of Action.

395. Under 15 U.S.C. § 2310(d)(1), Plaintiffs and Other Class Members were "damaged by the failure of a supplier, warrantor, or service contractor to comply with any obligation under this chapter, or under a written warranty, implied warranty, or service contract, may bring suit for damages and other legal and equitable relief." 15 U.S.C. § 2310(d)(1). Plaintiffs sue pursuant to this section to recover money damages and for legal and equitable relief on behalf of itself and the Class Members.

396. No Defendant has acted on the opportunity to cure its failure with respected to its warranted MCDs.

397. Likewise, pursuant to 15 U.S.C. § 2310(d)(2), upon prevailing in this action, Plaintiffs are entitled to receive an award of attorneys' fees and expenses and pray for the same.

SEVENTH COUNT
FRAUD
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

398. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

399. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

400. Defendants affirmatively misrepresented material facts including, inter alia, that their MCDs were therapeutically equivalent to their RLDs and/or complied with cGMPs and/or were not adulterated and/or misbranded.

401. Defendants omitted material facts including, inter alia, that their MCDs were not therapeutically equivalent to their RLDs and did not comply with cGMPs and/or were adulterated, misbranded, and/or unapproved.

402. Defendants' actions had the effect of fraudulently inducing customers to pay in whole or in part for Defendants' MCDs – products which Defendants knew or should have known were not therapeutically equivalent to their RLDs and/or did not comply with GMPs and/or were adulterated and/or misbranded. Plaintiffs and other Class Members would not have purchased Defendants' MCDs had they known the truth. Indeed, Plaintiffs and other Class Members could not have paid for Defendants' MCDs had they known the truth because Defendants' MCDs were illegally manufactured, illegally imported, illegally distributed, and illegally sold to Plaintiffs and Class Members based on Defendants' fraudulent misrepresentations and omissions.

403. Defendants knew, or reasonably should have known, that their misrepresentations were materially false or misleading, or that the omission of material facts rendered such representations false or misleading.

404. Defendants also knew, or had reason to know, that their misrepresentations and omissions would induce Class members to pay for some or all of the cost of Defendants' MCDs.

405. Defendants' misrepresentations and omissions were material.

406. Defendants' actively concealed their misrepresentations and omissions from the Class, government regulators, and the public.

407. To the extent applicable, Defendants intended their misrepresentations and omissions to induce Plaintiffs and other Class Members to pay for Defendants' MCDs.

408. But for these misrepresentations and omissions, Plaintiffs and other Class Members would have not have paid for Defendants' MCDs.

409. To the extent applicable, Plaintiffs and other Class Members were justified in relying on Defendants' misrepresentations and omissions. The same or substantively identical misrepresentations and omissions were communicated, to each Class member, including through product labeling and other statements by Defendants. No reasonable consumer would have paid what they did for Defendants' MCDs but for Defendants' unlawful conduct. To the extent applicable, reliance may be presumed in these circumstances.

410. Plaintiffs and other Class Members were damaged by reason of Defendants' misrepresentations and omissions alleged herein.

EIGHTH COUNT
FRAUD
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

411. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

412. This cause of action is alleged on behalf of TPP Class Members against all Defendants except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

413. Defendants affirmatively misrepresented material facts including, inter alia, that their MCDs were therapeutically equivalent to their RLDs and/or complied with cGMPs and/or were not adulterated and/or misbranded.

414. Defendants omitted material facts including, inter alia, that their MCDs were not therapeutically equivalent to their RLDs and did not comply with cGMPs and/or were adulterated, misbranded, and/or unapproved.

415. Defendants' actions had the effect of fraudulently inducing customers to pay in whole or in part for Defendants' MCDs – product which Defendants knew or should have known was not therapeutically equivalent to their RLDs and did not comply with GMPs and were adulterated and misbranded. Plaintiffs and other Class Members would not have paid some or all of the amounts they paid for Defendants' MCDs had they known the truth. Indeed, Plaintiffs and other Class Members could not have paid for Defendants' MCDs had they known the truth because Defendants' MCDs were illegally manufactured, illegally imported, illegally distributed, and illegally sold to Plaintiffs and Class Members based on Defendants' fraudulent misrepresentations and omissions.

416. Defendants knew, or reasonably should have known, that their misrepresentations were materially false or misleading, or that the omission of material facts rendered such representations false or misleading.

417. Defendants also knew, or had reason to know, that their misrepresentations and omissions would induce Class members to pay for some or all of the cost of Defendants' MCDs.

418. Defendants' misrepresentations and omissions were material.

419. Defendants actively concealed their misrepresentations and omissions from the Class, government regulators, and the public.

420. To the extent applicable, Defendants intended their misrepresentations and omissions to induce Plaintiffs and other Class Members to pay for Defendants' MCDs.

421. But for these misrepresentations and omissions, Plaintiffs and other Class Members would have not have paid for Defendants' MCDs.

422. To the extent applicable, Plaintiffs and other Class Members were justified in relying on Defendants' misrepresentations and omissions. The same or substantively identical misrepresentations and omissions were communicated to each Class member, including through product labeling and other statements by Defendants. No reasonable consumer would have paid what they did for Defendants' MCDs but for Defendants' unlawful conduct. To the extent applicable, reliance may be presumed in these circumstances.

423. Plaintiffs and other Class Members were damaged by reason of Defendants' misrepresentations and omissions alleged herein.

NINTH COUNT
NEGLIGENT MISREPRESENTATION AND OMISSION
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

424. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

425. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

426. Each Defendant had or undertook a duty to accurately and truthfully represent to the quality, nature, and characteristics of its MCDs.

427. Each Defendant failed to exercise ordinary care in making representations (or in failing to disclose facts) concerning the quality, nature, and characteristics of its MCDs.

428. Each Defendant negligently misrepresented or omitted facts regarding the quality, nature, and characteristics of its MCDs.

429. Each Defendant's statements were false at the time the misrepresentations were made (or at the time omissions were not made).

430. Each Defendant knew, or reasonably should have known, that its representations alleged herein were materially false or misleading, or that omission of material facts rendered such representations false or misleading. Each Defendant also knew, or had reason to know, that its misrepresentations and omissions would induce Class members to make purchases of each Defendant's MCDs.

431. As a direct and proximate result of each Defendant's acts and omissions described herein, Plaintiffs and other Class Members have suffered harm, and will continue to do so.

432. Each Defendant's misrepresentations or omissions were material and a substantial factor in Plaintiffs' and other Class Members' paying for MCDs.

433. Each Defendant intended its misrepresentations or omissions to induce Plaintiff and Class members to make purchases of MCDs, or had reckless disregard for same.

434. But for these misrepresentations (or omissions), Plaintiffs and other Class Members would not have made purchases of Defendants' MCDS.

435. Plaintiffs and other Class Members were justified in relying on Defendants' misrepresentations or omissions. The same or substantively identical misrepresentations were

communicated, and/or the same or substantively identical omissions were not communicated, to each Class Member.

436. Plaintiffs and other Class Members were damaged by reason of each Defendant's misrepresentations or omissions alleged herein.

TENTH COUNT
NEGLIGENT MISREPRESENTATION AND OMISSION (INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

437. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

438. This cause of action is alleged on behalf of TPP Class Members against all Defendants except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

439. Each Defendant had or undertook a duty to accurately and truthfully represent to the quality, nature, and characteristics of its MCDs.

440. Each Defendant failed to exercise ordinary care in making representations (or in failing to disclose facts) concerning the quality, nature, and characteristics of its MCDs.

441. Each Defendant negligently misrepresented or omitted facts regarding the quality, nature, and characteristics of its MCDs.

442. Each Defendant's statements were false at the time the misrepresentations were made (or at the time omissions were not made).

443. Each Defendant knew, or reasonably should have known, that its representations alleged herein were materially false or misleading, or that omission of material facts rendered such representations false or misleading. Each Defendant also knew, or had reason to know, that its misrepresentations and omissions would induce Class members to make purchases of each

Defendant's MCDs.

444. As a direct and proximate result of each Defendant's acts and omissions described herein, Plaintiffs and other Class Members have suffered harm, and will continue to do so.

445. Each Defendant's misrepresentations or omissions were material and a substantial factor in Plaintiffs' and other Class Members' paying for MCDs.

446. Each Defendant intended its misrepresentations or omissions to induce Plaintiff and Class members to make purchases of MCDs, or had reckless disregard for whether they would do so.

447. But for these misrepresentations (or omissions), Plaintiffs and other Class Members would not have purchased Defendants' MCDS.

448. Plaintiffs and other Class Members were justified in relying on Defendants' misrepresentations or omissions. The same or substantively identical misrepresentations were communicated, and/or the same or substantively identical omissions were not communicated, to each Class Member.

449. Plaintiffs and other Class Members were damaged by reason of each Defendant's misrepresentations or omissions alleged herein.

ELEVENTH COUNT
VIOLATION OF STATE CONSUMER PROTECTION LAWS
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

450. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

451. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

452. Each Defendant has violated the consumer protection statutes as follows:

a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, *et seq.*;

b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;

c. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Arizona Rev. Stat. § 44-1522, *et seq.*;

d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

e. Defendants have violated the California Unfair Competition Law by engaging in unfair or deceptive acts or practices in violation of Cal. Bus. Prof. Code § 17200, *et seq.*;

f. Defendants have violated the California Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750, *et seq.*;

g. Defendants have violated the California False Advertising Law, Cal. Bus. & Prof. Code §§ 17500, *et seq.*

h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

i. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

j. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*;

k. Defendants have engaged in unfair competition or unfair or deceptive acts

or practices in violation of D.C. Code § 28-3901, *et seq.*;

l. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

m. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. State 10-1-392, *et seq.*;

n. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

o. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;

p. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation 815 ILCS 505/1, *et seq.*;

q. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

r. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code Ann. § 714H, *et seq.*;

s. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

t. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

u. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;

v. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*; Defendants have

engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

w. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

x. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;

y. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

z. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, *et seq.*;

aa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.0 10, *et seq.*;

bb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;

cc. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

dd. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

ee. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

ff. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;

gg. Defendants have engaged in unfair competition or unfair or deceptive acts or

practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

hh. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

ii. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 350, et seq.;

jj. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

kk. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

ll. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*

mm. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

nn. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

oo. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

pp. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, *et seq.*;

qq. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

rr. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

ss. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

tt. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

uu. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-11-1, *et seq.*;

vv. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. Tit. 9, § 2451, *et seq.*;

ww. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;

xx. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*; Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

yy. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*;

zz. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*; and

aaa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 23 L.P.R.A. § 1001, *et seq.*, the applicable statute for the Commonwealth of Puerto Rico.

453. Each Defendant's conduct constitutes trade or commerce or other actionable activity within the meaning of the above statutes.

454. Each Plaintiff and other Class Member is a consumer or person aggrieved by Defendants' misconduct within the meaning of the above statutes.

455. To the extent applicable, each Defendant knew, intended, or should have known that their fraudulent and deceptive acts, omissions, or concealment would induce reliance and that reliance can be presumed under the circumstances. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiffs and other Class Members have suffered damages– an ascertainable loss – in an amount to be proved at trial.

TWELFTH COUNT
VIOLATION OF STATE CONSUMER PROTECTION LAWS (INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

456. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

457. This cause of action is alleged on behalf of TPP Class Members against all Defendants except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

458. Each Defendant has violated the consumer protection statutes as follows:

a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, *et seq.*;

b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;

c. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Arizona Rev. Stat. § 44-1522, *et seq.*;

d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

e. Defendants have violated the California Unfair Competition Law by engaging in unfair or deceptive acts or practices in violation of Cal. Bus. Prof. Code § 17200, *et seq.*;

f. Defendants have violated the California Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750, *et seq.*;

g. Defendants have violated the California False Advertising Law, Cal. Bus. & Prof. Code §§ 17500, *et seq.*

h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

i. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

j. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*;

k. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*;

l. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

m. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. State 10-1-392, *et seq.*;

n. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

o. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;

p. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation 815 ILCS 505/1, *et seq.*;

q. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

r. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code Ann. § 714H, *et seq.*;

s. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

t. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

u. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;

v. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*; Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

w. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

x. Defendants have engaged in unfair competition or unfair or deceptive acts or

practices in violation of Mich. Stat. § 445.901, *et seq.*;

y. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

z. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, *et seq.*;

aa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.0 10, *et seq.*;

bb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;

cc. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

dd. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

ee. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

ff. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;

gg. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

hh. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

ii. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 350, et seq.;

jj. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

kk. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

ll. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*

mm. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

nn. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

oo. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

pp. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, *et seq.*;

qq. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

rr. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

ss. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

tt. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

uu. Defendants have engaged in unfair competition or unfair or deceptive acts or

practices in violation of Utah Code Ann. § 13-11-1, *et seq.*;

vv. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. Tit. 9, § 2451, *et seq.*;

ww. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;

xx. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*; Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

yy. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*;

zz. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*; and

aaa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 23 L.P.R.A. § 1001, *et seq.*, the applicable statute for the Commonwealth of Puerto Rico.

459. Each Defendant's conduct constitutes trade or commerce or other actionable activity within the meaning of the above statutes.

460. Each Plaintiff and other Class Member is a consumer or persons aggrieved by Defendants' misconduct within the meaning of the above statutes.

461. To the extent applicable, each Defendant knew, intended, or should have known that their fraudulent and deceptive acts, omissions, or concealment would induce reliance and that reliance can be presumed under the circumstances. As a direct and proximate result of Defendants'

unfair methods of competition and unfair or deceptive acts or practices, Plaintiffs and other Class Members have suffered damages– an ascertainable loss – in an amount to be proved at trial.

THIRTEENTH COUNT
UNJUST ENRICHMENT
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

462. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

463. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

464. As alleged herein, Defendants were unjustly enriched at the expense of Plaintiffs and other Class Members by virtue of the latter's paying for Defendants' MCDs.

465. Defendants profited immensely from introducing a carcinogen into the United States for human consumption. On top of that, because Defendants' MCDs were adulterated and misbranded, their distribution and sale in the United States was illegal.

466. Plaintiffs and other Class Members were unjustly deprived of money obtained by Defendants as a result of the improper amounts paid for Defendants' MCDs. It would be inequitable and unconscionable for Defendants to retain the profit, benefit, and other compensation obtained from Plaintiffs and other Class Members as a result of their wrongful conduct alleged in this Complaint.

467. Plaintiffs and other Class Members are entitled to seek and do seek restitution from Defendants as well as an order from this Court requiring disgorgement of all profits, benefits, and other compensation obtained by Defendants by virtue of its wrongful conduct.

FOURTEENTH COUNT
UNJUST ENRICHMENT
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

468. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

469. This cause of action is alleged on behalf of TPP Class Members against all Defendants except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

470. As alleged herein, Defendants were unjustly enriched at the expense of Plaintiffs and other Class Members by virtue of the latter's paying for Defendants' MCDs.

471. Defendants profited immensely from introducing a carcinogen into the United States for human consumption. On top of that, because Defendants' MCDs were adulterated and/or misbranded, their distribution and sale in the United States was illegal.

472. Plaintiffs and other Class Members were unjustly deprived of money obtained by Defendants as a result of the improper amounts paid for Defendants' MCDs. It would be inequitable and unconscionable for Defendants to retain the profit, benefit, and other compensation obtained from Plaintiffs and other Class Members as a result of their wrongful conduct alleged in this Complaint.

473. Plaintiffs and other Class Members are entitled to seek and do seek restitution from Defendants as well as an order from this Court requiring disgorgement of all profits, benefits, and other compensation obtained by Defendants by virtue of its wrongful conduct.

FIFTEENTH COUNT
NEGLIGENCE
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

474. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

475. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

476. Each Defendant owed a duty to Plaintiffs and the Class to use and exercise reasonable and due care in the manufacturing of its MCDs.

477. Each Defendant owed a duty to Plaintiffs and the Class to ensure that the MCDs it sold in the United States were therapeutically equivalent to their RLDs and complied with cGMPs and were not adulterated or misbranded.

478. Each Defendant owed a duty to care to Plaintiffs and the Class because they were the foreseeable, reasonable, and probable user of MCDs and victim of each Defendant's fraudulent and deceptive activities. Each Defendant knew, or should have known, that its MCDs were not therapeutically equivalent to their RLDs and did not comply with cGMPs and were adulterated and misbranded, and each was in the best position to uncover and remedy these shortcomings.

479. Each Defendant failed to do this. Each Defendant inadequately oversaw the manufacture and sale of its own MCDs. Each Defendant knew that ignoring the manufacturing issues surrounding its MCDs would damage Plaintiffs and the Class and increase its own profits.

480. Each Defendant maintained or should have maintained a special relationship with Plaintiffs and the Class, as they were obligated to ensure that its MCDs complied with cGMPs and was not adulterated or misbranded.

481. Each Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiffs and the Class. Each Defendant's misconduct included, but was not limited to, failing to oversee actions taken in the manufacture and sale of its MCDs.

482. Each Defendant breached duties owed to Plaintiffs and the Class by failing to exercise reasonable care sufficient to protect the interests and meet the needs of Plaintiffs and the Class.

483. As a direct and proximate result of each Defendant's negligent conduct, Plaintiffs and the Class has suffered injury and are entitled to damages in an amount to be proven at trial.

SIXTEENTH COUNT
NEGLIGENCE
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

484. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

485. This cause of action is alleged on behalf of TPP Class Members against all Defendants except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

486. Each Defendant owed a duty to Plaintiffs and the Class to use and exercise reasonable and due care in the manufacturing of its MCDs.

487. Each Defendant owed a duty to Plaintiffs and the Class to ensure that the MCDs it sold in the United States were therapeutically equivalent to their RLDs and complied with cGMPs and were not adulterated or misbranded.

488. Each Defendant owed a duty to care to Plaintiffs and the Class because they were the foreseeable, reasonable, and probable user of MCDs and victim of each Defendant's fraudulent and deceptive activities. Each Defendant knew, or should have known, that its MCDs were not therapeutically equivalent to their RLDs and did not comply with cGMPs and were adulterated and misbranded, and each was in the best position to uncover and remedy these shortcomings.

489. Each Defendant failed to do this. Each Defendant inadequately oversaw the

manufacture and sale of its own MCDs. Each Defendant knew that ignoring the manufacturing issues surrounding its MCDs would damage Plaintiffs and the Class and increase its own profits.

490. Each Defendant maintained or should have maintained a special relationship with Plaintiffs and the Class, as they were obligated to ensure that its MCDs complied with cGMPs and were not adulterated or misbranded.

491. Each Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiffs and the Class. Each Defendant's misconduct included, but was not limited to, failing to oversee actions taken in the manufacture and sale of its MCDs.

492. Each Defendant breached the duties owed to Plaintiffs and the Class by failing to exercise reasonable care sufficient to protect the interests and meet the needs of Plaintiffs and the Class.

493. As a direct and proximate result of each Defendant's negligent, and possibly grossly negligent conduct, Plaintiffs and the Class has suffered injury and are entitled to damages in an amount to be proven at trial.

SEVENTEENTH COUNT
NEGLIGENCE PER SE
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

494. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

495. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

496. Each Defendant owed a duty to Plaintiffs and the Class to use and exercise reasonable and due care in the manufacturing of its MCDs.

497. Each Defendant owed a duty to Plaintiffs and the Class to ensure that the MCDs it

sold in the United States were therapeutically equivalent to their RLDs and complied with cGMPs and were not adulterated or misbranded.

498. Each Defendant owed a duty to Plaintiffs and the Class because each state, territory, and possession has adopted /or adheres to federal cGMP and adulteration standards, including but not limited to the following parallel state statutes:

- Alabama Code §§ 20-1-24 and -27(1);
- Alaska Statutes § 17.20.290(a)(1);
- Arizona Statutes §§ 32-1965(1), (2) and -1966(3);
- Arkansas Code § 20-56-215(1);
- California Health and Safety Code §§ 111295 and 111400;
- Colorado Statutes §§ 25-5-403(1)(a),(b) and -414(1)(c);
- Title 16, Delaware Code §§ 3302 and 3303(2);
- District of Columbia Code § 48-702(2);
- Florida Statutes §§ 499.005(1) and .006(3);
- Georgia Code § 26-3-3(1);
- Hawaii Revised Statutes §§ 328-6(1) and -14(1)(B)(ii);
- Idaho Code § 37-115(a);
- Chapter 410, Illinois Statutes §§ 620/3.1 and /14(a)(2)(B);
- Iowa Code §§ 126.3(1) and .9(1)(c);
- Kentucky Statutes § 217.175(1);
- Maryland Code, Health–General §§ 21-216(c)(5)(2) and -256(1);
- Massachusetts General Laws chapter 94 §§ 186 and 190;
- Minnesota Statutes §§ 151.34(1) and .35(1);
- Missouri Statutes § 196.015(1);
- Montana Code §§ § 50-31-305(3) and -501(1);
- Nebraska Revised Statutes §§ 71-2461(2) and -2481;
- Nevada Statutes § 585.520(1);
- New Hampshire Revised Statutes §§ 146:1(I) and :4(V);

- New Mexico Statutes §§ 26-1-3(A) and -10(A);
- New York Education Law § 6811;
- North Dakota Century Code §§ 19-02.1-02(1) and .1-13(3);
- Ohio Code § 3715.52(A)(1);
- Oklahoma Statutes title 63 § 1-1402(a);
- Title 35, Pennsylvania Statutes § 780-113(a)(1);
- Title 21, Rhode Island General Laws § 21-3-3(1);
- South Carolina Code §§ 39-23-30(a)(2)(B) and -80(A)(1);
- South Dakota Code §§ 39-15-3 and -10;
- Title 18, Vermont Statutes § 4052(1);
- Virginia Code § 54.1-3457(1);
- West Virginia Code §§ 16-7-1 and -2(a)(3); and
- Wyoming Statutes §§ 35-7-111(a)(i)–(iv), (vi) and -116.

499. Each Defendant failed to comply with federal cGMPs and federal adulteration standards.

500. As a result of each Defendant's failures to do so, each Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiffs and the Class.

501. As a direct and proximate result of each Defendant's negligent conduct, Plaintiffs and the Class have suffered injury and are entitled to damages in an amount to be proven at trial.

EIGHTEENTH COUNT
NEGLIGENCE PER SE
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

502. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

503. This cause of action is alleged on behalf of TPP Class Members against all Defendants except Pharmacy Defendants, and to the extent applicable law permits non-consumers

to assert this cause of action.

504. Each Defendant owed a duty to Plaintiffs and the Class to use and exercise reasonable and due care in the manufacturing of its MCDs.

505. Each Defendant owed a duty to Plaintiffs and the Class to ensure that the MCDs it sold in the United States were therapeutically equivalent to their RLDs and complied with cGMPs and were not adulterated or misbranded.

506. Each Defendant owed a duty to Plaintiffs and the Class because each state, territory, and possession has adopted or adheres to federal cGMP and adulteration standards, including but not limited to the following parallel state statutes:

- Alabama Code §§ 20-1-24 and -27(1);
- Alaska Statutes § 17.20.290(a)(1);
- Arizona Statutes §§ 32-1965(1), (2) and -1966(3);
- Arkansas Code § 20-56-215(1);
- California Health and Safety Code §§ 111295 and 111400;
- Colorado Statutes §§ 25-5-403(1)(a),(b) and -414(1)(c);
- Title 16, Delaware Code §§ 3302 and 3303(2);
- District of Columbia Code § 48-702(2);
- Florida Statutes §§ 499.005(1) and .006(3);
- Georgia Code § 26-3-3(1);
- Hawaii Revised Statutes §§ 328-6(1) and -14(1)(B)(ii);
- Idaho Code § 37-115(a);
- Chapter 410, Illinois Statutes §§ 620/3.1 and /14(a)(2)(B);
- Iowa Code §§ 126.3(1) and .9(1)(c);
- Kentucky Statutes § 217.175(1);
- Maryland Code, Health–General §§ 21-216(c)(5)(2) and -256(1);
- Massachusetts General Laws chapter 94 §§ 186 and 190;
- Minnesota Statutes §§ 151.34(1) and .35(1);

- Missouri Statutes § 196.015(1);
- Montana Code §§ § 50-31-305(3) and -501(1);
- Nebraska Revised Statutes §§ 71-2461(2) and -2481;
- Nevada Statutes § 585.520(1);
- New Hampshire Revised Statutes §§ 146:1(I) and :4(V);
- New Mexico Statutes §§ 26-1-3(A) and -10(A);
- New York Education Law § 6811;
- North Dakota Century Code §§ 19-02.1-02(1) and .1-13(3);
- Ohio Code § 3715.52(A)(1);
- Oklahoma Statutes title 63 § 1-1402(a);
- Title 35, Pennsylvania Statutes § 780-113(a)(1);
- Title 21, Rhode Island General Laws § 21-3-3(1);
- South Carolina Code §§ 39-23-30(a)(2)(B) and -80(A)(1);
- South Dakota Code §§ 39-15-3 and -10;
- Title 18, Vermont Statutes § 4052(1);
- Virginia Code § 54.1-3457(1);
- West Virginia Code §§ 16-7-1 and -2(a)(3); and
- Wyoming Statutes §§ 35-7-111(a)(i)–(iv), (vi) and -116.

507. Each Defendant failed to comply with federal cGMPs and federal adulteration standards.

508. As a result of each Defendant's failures to do so, each Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiffs and the Class.

509. As a direct and proximate result of each Defendant's negligent conduct, Plaintiffs and the Class has suffered injury and are entitled to damages in an amount to be proven at trial.

NINETEENTH COUNT
VIOLATION OF CALIFORNIA'S CONSUMERS LEGAL REMEDIES ACT,
Cal. Civ. Code §§ 1750, *et seq.*
(On Behalf of the California Subclass)

510. Plaintiffs hereby incorporate by reference and re-allege herein all paragraphs alleged above.

511. This Count is brought by all Plaintiffs listed on this Complaint who are from the State of California (for the purposes of this count only, "Plaintiffs").

512. Plaintiffs bring this claim individually and on behalf of the members of the proposed California Subclass against Defendants Amneal, AvKare, Avet, and Aurobindo (for the purposes of this count only, "Defendants").

513. California's Consumers Legal Remedies Act ("CLRA"), Cal Civ. Code §1750, et seq., prohibits "unfair methods of competition and unfair or deceptive acts or practices undertaken by any person in a transaction intended to result or which results in the sale or lease of goods or services to any consumer." Cal. Civ. Code § 1770(a).

514. Plaintiffs and members of the California Subclass are "consumers" within the meaning of Cal. Civ. Code § 1761(d) because they bought MCDs for personal, family, or household purposes.

515. Defendants are "persons" within the meaning of California Civil Code sections 1761(c) and 1770 and provided "goods" within the meaning of sections 1761(a) and 1770.

516. Plaintiffs, the other members of the California Subclass, and Defendant have engaged in "transactions," as that term is defined by California Civil Code § 1761(e).

517. Defendants' acts and practices, as alleged in this complaint, violate the CLRA because they include unfair and deceptive acts and practices in connection with transactions (the sale of MCDs).

518. As alleged more fully above, Defendants violated the CLRA by falsely representing to Plaintiffs and the other members of the California Subclass that MCDs (i) would not contain elevated levels of NDMA and (ii) are generally recognized as safe for human consumption. In fact, the MCDs contained elevated levels of NDMA and was not safe for human consumption.

519. These misrepresentations constitute "unfair or deceptive acts or practices" that are prohibited by the CLRA, Cal. Civ. Code §§ 1770(a)(5); 1770 (a)(7); 1770(a)(9); and 1770(a)(16).

520. Further, Defendants concealed from and failed to disclose to Plaintiffs and the California Subclass that their MCDs did not conform to the product's labels, packaging, advertising, and statements in that it contained elevated levels of NDMA and was not safe for human consumption.

521. Defendants had a duty to disclose to Plaintiffs and members of the California Subclass the true quality, characteristics, ingredients, nutrient levels, and suitability of the MCDs because Defendants were in a superior position to know the true nature of their products and Defendants knew that Plaintiffs and members of the California Subclass could not reasonably have been expected to learn or discover that the MCDs was misrepresented in the packaging, labels, advertising, and websites prior to purchasing the MCDs.

522. The facts concealed or not disclosed by Defendants to Plaintiffs and members of the California Subclass were material in that a reasonable consumer would have considered them important when deciding whether to purchase the MCDs.

523. Plaintiffs and California Subclass members' reliance on these omissions was reasonable given Defendants' advertising, representations, warranties, and general promotions of MCDs.

524. Plaintiffs and members of the California Subclass did not know that Defendants

were concealing or otherwise omitting material facts.

525. As a direct and proximate result of Defendants' violations, Plaintiffs and the California Subclass are entitled to injunctive relief ensuring Defendant issues a recall of its MCDs medications and complies with all proper quality and safety standards going forward.

526. On March 27, 2020 and April 7, 2020, prior to filing this action, CLRA notice letters were sent to Defendants that comply in all respects with California Civil Code § 1782(a). Plaintiffs' counsel sent Defendants the letter via certified mail, return receipt requested, advising Defendants that they are in violation of the CLRA and demanding that it cease and desist from such violations. A true and correct copy of Plaintiffs' CLRA letters are attached hereto as Exhibit A.

TWENTIETH COUNT
VIOLATION OF CALIFORNIA'S UNFAIR COMPETITION LAW,
California Business & Professions Code §§ 17200, *et seq.*
(On Behalf of the California Subclass)

527. Plaintiffs hereby incorporate by reference and re-allege herein all paragraphs alleged above.

528. This Count is brought by all Plaintiffs listed on this Complaint who are from the State of California (for the purposes of this count only, "Plaintiffs").

529. Plaintiffs bring this claim individually and on behalf of the members of the proposed California Subclass against Defendants Amneal, AvKare, Avet, and Aurobindo (for the purposes of this count only, "Defendants").

530. Defendant is subject to the Unfair Competition Law ("UCL"), Bus. & Prof. Code §§ 17200 et seq. The UCL provides, in pertinent part: "Unfair competition shall mean and include unlawful, unfair or fraudulent business practices and unfair, deceptive, untrue or misleading advertising …."

531. By committing the acts and practices alleged herein, Defendants violated

California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200, et seq. as to the Class, by engaging in unlawful, fraudulent, and unfair conduct.

532. Defendants violated the UCL's proscription against engaging in unlawful conduct as a result of its violations of the CLRA, Cal. Civil Code §§ 1770(a)(5), (a)(7), (a)(9), and (a)(16).

533. Defendant's acts, omissions, misrepresentations, practices, and non-disclosures concerning the Supplements, as alleged herein, constitute "unlawful" business acts and practices in that they violate the FDCA and implementing regulations, including, at least, the following sections:

a. Failure to comply with cGMPs to ensure that the MCDs met safety, quality, purity, identity, and strength standards. 21 U.S.C. § 351(a)(2)(B); 21 C.F.R. § 210.1(a); and

b. The prohibition on introduction of adulterated and misbranded medications into interstate commerce. 21 U.S.C. §§ 331, 351-352.

534. Each of Defendants' violations of federal law and regulations violates California's Sherman Food, Drug, and Cosmetic Law, Cal. Health & Safety Code § 109875 et seq. (the "Sherman Law"), including, but not limited to, the following sections:

a. Section 110100 (adopting all FDA regulations as state regulations);

b. Section 111260 ("Any drug or device is adulterated if the methods, facilities, or controls used for its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with current good manufacturing practice to assure that the drug or device meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess.");

c. Section 111280 ("Any drug is adulterated if it purports to be, or is represented as, a drug that is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standards set forth in the compendium.");

d. Section 111295 ("It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.");

e. Section 111305 ("It is unlawful for any person to receive in commerce any drug or device that is adulterated or to deliver or proffer for delivery any drug or device.");

f. Section 111330 ("Any drug or device is misbranded if its labeling is false or misleading in any particular.");

535. Each of the challenged omissions, statements, and actions by Defendants violates the FDCA and the Sherman Law, and, consequently, violates the "unlawful" prong of the UCL.

536. Defendants' acts and practices described above violate the UCL's proscription against engaging in fraudulent conduct.

537. Specifically, Defendants marketed MCDs as safe for human consumption. As indicated above, however, these representations are false and misleading as Defendants' MCDs contained elevated levels of NDMA. These representations were likely to deceive reasonable consumers.

538. Defendants' acts and practices described above also violate the UCL's proscription against engaging in unfair conduct.

539. Plaintiffs and the other California Subclass members suffered a substantial injury by virtue of buying MCDs that they would not have purchased absent Defendants' unlawful, fraudulent, and unfair marketing, advertising, packaging, and omission about the contaminated nature of its MCDs medication, or by virtue of paying an excessive premium price for the

unlawfully, fraudulently, and unfairly marketed, advertised, packaged, and labeled MCDs medication.

540. There is no benefit to consumers or competition from deceptively marketing and omitting material facts about the contaminated nature of the MCDs.

541. Plaintiffs and the other California Subclass members had no way of reasonably knowing that the MCDs they purchased was not as marketed, advertised, packaged, or labeled. Plaintiffs and the other California Subclass members are not able to test for the presence of NDMA in their MCDs. Thus, Plaintiffs and the other California Subclass members could not have reasonably avoided the injury each of them suffered.

542. The gravity of the consequences of Defendants' conduct as described above outweighs any justification, motive, or reason therefore, particularly considering the available legal alternatives which exist in the marketplace, and such conduct is immoral, unethical, unscrupulous, offends established public policy, or is substantially injurious to Plaintiffs and the other members of the California Subclass.

543. Defendants' violations have continuing and adverse effects because Defendants' unlawful conduct is continuing, with no indication that Defendants intend to cease this fraudulent course of conduct. The public and class members are subject to ongoing harm because Defendants, other than Defendant Amneal, have not issued a recall for its contaminated MCDs medication. Further, although Defendant Amneal has issued a recall, it has not provided compensation to Plaintiffs for their contaminated MCDs, and Plaintiffs were forced to spend more money to purchased uncontaminated MCDs.

544. Plaintiffs and the California Subclass lost money or property as a result of Defendants' UCL violations because: (a) they would not have purchased MCDs on the same terms

if they knew that the MCDs contained harmful levels of NDMA, and are not generally recognized as safe for human consumption; and (b) the MCDs do not have the characteristics, ingredients, uses, or benefits as promised by Defendants.

545. Pursuant to California Business and Professional Code § 17203, Plaintiffs and the California Subclass seek an order of this Court that includes, but is not limited to, an order requiring Defendants to: (a) provide restitution to Plaintiffs and the other California Subclass members; (b) disgorge all revenues obtained as a result of violations of the UCL; and (c) pay Plaintiffs' and the California Subclass' attorney's fees and costs.

TWENTY-FIRST COUNT
VIOLATION OF NEW YORK GENERAL BUSINESS LAW § 349
(On Behalf Of The New York Subclass)

546. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

547. This Count is brought by all Plaintiffs listed on this Complaint who are from the State of New York (for the purposes of this count only, "Plaintiffs").

548. Plaintiffs bring this claim individually and on behalf of the members of the proposed New York Subclass against Defendants Ascend and Alkem (for the purposes of this count only, "Defendants").

549. New York's General Business Law § 349 prohibits deceptive acts or practices in the conduct of any business, trade, or commerce.

550. In its sale of goods throughout the State of New York, Defendants conduct business and trade within the meaning and intendment of New York's General Business Law § 349.

551. Plaintiffs and members of the New York Subclass are consumers who purchased products from Defendants for their personal use.

552. By the acts and conduct alleged herein, Defendants engaged in deceptive, unfair, and misleading acts and practices, which include, without limitation, misrepresenting that the MCDs (i) would not contain dangerously high levels of NDMA and (ii) are generally recognized as safe for human consumption. Defendants intentionally concealed and omitted material facts regarding the true nature of the medications.

553. The foregoing deceptive acts and practices were directed at consumers.

554. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the characteristics and quality of the MCDs to induce consumers to purchase the same.

555. By reason of this conduct, Defendants engaged in deceptive conduct in violation of New York's General Business Law.

556. Defendants' actions are the direct, foreseeable, and proximate cause of the damages that Plaintiffs and members of the New York Subclass have sustained from having paid for and used Defendants' products.

557. As a result of Defendants' violations, Plaintiffs and members of the New York Subclass have suffered damages because: (a) they would not have purchased the MCDs on the same terms if they knew that the MCDs contained high levels of NDMA; and (b) Plaintiffs paid a premium price in the amount of the full purchase price of the products, and (c) the MCDs do not have the characteristics, uses, benefits, or qualities as promised.

558. On behalf of themselves and other members of the New York Subclass, Plaintiffs seek to recover their actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

TWENTY-SECOND COUNT
VIOLATION OF NEW YORK GENERAL BUSINESS LAW § 350
(On Behalf Of The New York Subclass)

559. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

560. This Count is brought by all Plaintiffs listed on this Complaint who are from the State of New York (for the purposes of this count only, "Plaintiffs").

561. Plaintiffs bring this claim individually and on behalf of the members of the proposed New York Subclass against Defendants Ascend and Alkem (for the purposes of this count only, "Defendants").

562. New York's General Business Law § 350 prohibits false advertising in the conduct of any business, trade, or commerce.

563. Pursuant to said statute, false advertising is defined as "advertising, including labeling, of a commodity … if such advertising is misleading in a material respect."

564. Based on the foregoing, Defendants engaged in consumer-oriented conduct that is deceptive or misleading in a material way which constitutes false advertising in violation of Section 350 of New York's General Business Law.

565. Defendants' false, misleading, and deceptive statements and representations of fact were and are directed towards consumers. Defendants also actively concealed and knowingly admitted material facts regarding the true nature of the MCDs.

566. Defendants' false, misleading, and deceptive statements and representations of fact and omissions were and are likely to mislead a reasonable consumer acting reasonably under the circumstances.

567. Defendants' false, misleading, and deceptive statements and representations of fact

and omissions have resulted in consumer injury or harm to the public interest.

568. As a result of Defendants' false, misleading, and deceptive statements and representations of fact, and omissions, Plaintiffs and the New York Subclass have suffered and continue to suffer economic injury.

569. As a result of Defendants' violations, Plaintiffs and members of the New York Subclass have suffered damages due to said violations because: (a) they would not have purchased the MCDs on the same terms if they knew that the MCDs contained elevated levels of NDMA and are not safe for human consumption; (b) Plaintiffs paid a premium price in the amount of the full purchase price of the products; and (c) the MCDs do not have the characteristics, uses, benefits, or qualities as promised.

570. On behalf of themselves and other members of the New York Subclass, Plaintiffs seeks to recover their actual damages or five hundred dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

PRAYER FOR RELIEF

For these reasons, Plaintiffs pray for the following judgment:

A. An order certifying this action as a class action;

B. An order appointing Plaintiffs as Class Representatives, and appointing undersigned counsel as Class Counsel to represent the Class;

C. A declaration that Defendants are liable under each and every one of the above-enumerated causes of action;

D. An order awarding appropriate preliminary and/or final injunctive relief against the conduct of Defendants described above;

E. Payment to Plaintiffs and Class Members of all damages, exemplary or punitive damages, and/or restitution associated with the conduct for all causes of action in an amount to be proven at trial, including but not limited to the full amounts paid or reimbursed for the MCDs; the costs to replace or return MCDs because of recalls; and/or the increases in the amounts paid for non-adulterated, non-misbranded, MCDs in the wake of the recalls;

F. An award of attorneys' fees, expert witness fees, and costs, as provided by applicable law and/or as would be reasonable from any recovery of monies recovered for or benefits bestowed on the Class Members;

G. An award of statutory penalties to the extent available;

H. Interest as provided by law, including but not limited to pre-judgment and post-judgment interest as provided by rule or statute; and

I. Such other and further relief as this Court may deem just, equitable, or proper.

JURY DEMAND

Plaintiffs respectfully request a trial by jury on all causes of action so triable.

Dated: July 6, 2020

Respectfully Submitted,

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CERTIFICATE OF SERVICE

A true and correct copy of the foregoing was served this 6th day of July, 2020, on all counsel of record via the CM/ECF system of the United States District Court for the District of New Jersey.

/s/ David J. Stanoch
David J. Stanoch